



Dutch ICH Surgery Trial

Dutch ICH Surgery Trial (DIST):

A prospective, multicenter, randomized, open clinical trial with blinded end-point assessment of minimally invasive endoscopy-guided surgery in patients with spontaneous, supratentorial intracerebral hemorrhage.

Case Report Forms (CRFs) ON PAPER

Version 2.0, March 2023

Study number: _ _ _ _ _

Inclusion date (DD/MM/YY): _ / _ / _ _

*Please complete all forms as fully as possible.
Thank you for your cooperation.*

Kind regards,

The DIST team

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www.dutch-ich.nl

Study number:

Date of inclusion: ___/___/___

BASELINE CRF

Demographics

Ethnicity/race	<input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Asian <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Mixed <input type="checkbox"/> Other: _____
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Medical history/comorbidities at baseline

Medical history of:	
Atrial fibrillation or flutter	<input type="checkbox"/> No <input type="checkbox"/> Yes
Chronic heart failure	<input type="checkbox"/> No <input type="checkbox"/> Yes
Deep venous thrombosis	<input type="checkbox"/> No <input type="checkbox"/> Yes
Pulmonary embolism	<input type="checkbox"/> No <input type="checkbox"/> Yes
Diabetes mellitus	<input type="checkbox"/> No <input type="checkbox"/> Yes (on treatment for diabetes or 2x fasting glucose >7 mmol/l)
Hypertension	<input type="checkbox"/> No <input type="checkbox"/> Yes (on treatment for hypertension or known with high blood pressure (2x SBP >140 or DBP >90 mm Hg))
Hypercholesterolemia	<input type="checkbox"/> No <input type="checkbox"/> Yes (using lipid-lowering drugs or total cholesterol >6.2 mmol/l)
Labile INR	<input type="checkbox"/> No <input type="checkbox"/> Yes (unstable/high INRs, time in therapeutic range <60%)
Liver disease	<input type="checkbox"/> No <input type="checkbox"/> Yes: <u>Specify:</u> Liver cirrhosis <input type="checkbox"/> No <input type="checkbox"/> Yes Other, please specify: _____
Renal disease	<input type="checkbox"/> No <input type="checkbox"/> Yes: <u>Specify:</u> Dialysis <input type="checkbox"/> No <input type="checkbox"/> Yes Renal transplant <input type="checkbox"/> No <input type="checkbox"/> Yes Other, please specify: _____
Previous intracerebral hemorrhage	<input type="checkbox"/> No <input type="checkbox"/> Yes
Ischemic stroke	<input type="checkbox"/> No <input type="checkbox"/> Yes
Transient ischemic attack	<input type="checkbox"/> No <input type="checkbox"/> Yes
Prior major bleeding	<input type="checkbox"/> No <input type="checkbox"/> Yes
Predisposition to bleeding	<input type="checkbox"/> No <input type="checkbox"/> Yes
Mechanical aorta and/or mitral valve replacement	<input type="checkbox"/> No <input type="checkbox"/> Yes
Myocardial infarction	<input type="checkbox"/> No <input type="checkbox"/> Yes
Peripheral artery disease	<input type="checkbox"/> No <input type="checkbox"/> Yes
Premorbid cognitive complaints	<input type="checkbox"/> No <input type="checkbox"/> Yes
Falls in the past year	<input type="checkbox"/> No <input type="checkbox"/> Yes: <u>Specify: number of falls</u> _____
Comorbidity influencing mRS	<input type="checkbox"/> No <input type="checkbox"/> Yes: <u>Specify:</u> _____

Intoxication(s):

Smoking status	<input type="checkbox"/> Never <input type="checkbox"/> Current <input type="checkbox"/> Stopped < 6 months ago <input type="checkbox"/> Stopped > 6 months ago
Use of alcohol	<input type="checkbox"/> No <input type="checkbox"/> Yes: units/week: _____
Use of drugs	<input type="checkbox"/> No <input type="checkbox"/> Yes: <u>Specify:</u> Amphetamines <input type="checkbox"/> No <input type="checkbox"/> Yes Cannabis <input type="checkbox"/> No <input type="checkbox"/> Yes Cocaine <input type="checkbox"/> No <input type="checkbox"/> Yes GHB <input type="checkbox"/> No <input type="checkbox"/> Yes MDMA (XTC) <input type="checkbox"/> No <input type="checkbox"/> Yes Opiates <input type="checkbox"/> No <input type="checkbox"/> Yes Other: _____

Medication (home) – use of:

Antihypertensive drug(s)	<input type="checkbox"/> No <input type="checkbox"/> Yes: <u>Specify:</u> ACE-inhibitor (e.g. lisinopril, enalapril) <input type="checkbox"/> No <input type="checkbox"/> Yes Angiotensin II rec antagonist (e.g. losartan) <input type="checkbox"/> No <input type="checkbox"/> Yes Beta blocker (e.g. metoprolol, atenolol) <input type="checkbox"/> No <input type="checkbox"/> Yes Calcium channel blocker (e.g. amlodipine) <input type="checkbox"/> No <input type="checkbox"/> Yes Diuretic (e.g. furosemide, hydrochlorothiazide) <input type="checkbox"/> No <input type="checkbox"/> Yes Other: _____
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Study number:

Date of inclusion: ___/___/___

Antiplatelet agent(s)	<input type="checkbox"/> No <input type="checkbox"/> Yes:	Specify: Acetylsalicylic acid/carbasalate calcium <input type="checkbox"/> No <input type="checkbox"/> Yes Clopidogrel <input type="checkbox"/> No <input type="checkbox"/> Yes Dipyridamole <input type="checkbox"/> No <input type="checkbox"/> Yes Ticagrelor <input type="checkbox"/> No <input type="checkbox"/> Yes Other: _____
Vitamin K antagonist	<input type="checkbox"/> No <input type="checkbox"/> Yes:	Specify: Acenocoumarol <input type="checkbox"/> No <input type="checkbox"/> Yes Phenprocoumon <input type="checkbox"/> No <input type="checkbox"/> Yes
Direct oral anticoagulant (DOAC)	<input type="checkbox"/> No <input type="checkbox"/> Yes:	Specify: Dabigatran (Pradaxa®) <input type="checkbox"/> No <input type="checkbox"/> Yes Other: _____ Other DOACs (anti-Xa inhibitors: apixaban, edoxaban, rivaroxaban) are an exclusion criterion, re-evaluate
Therapeutic heparin (all types, including LMWH)	<input type="checkbox"/> No <input type="checkbox"/> Yes	Usage of therapeutic heparin is an exclusion criterion, re-evaluate. Prophylactic heparin is allowed.
NSAID (daily in last 7 days)	<input type="checkbox"/> No <input type="checkbox"/> Yes	
Statin	<input type="checkbox"/> No <input type="checkbox"/> Yes	
Immunosuppressive- or modulating drugs	<input type="checkbox"/> No <input type="checkbox"/> Yes:	Specify: Corticosteroid <input type="checkbox"/> No <input type="checkbox"/> Yes Interleukin inhibitor <input type="checkbox"/> No <input type="checkbox"/> Yes Calcineurin inhibitor <input type="checkbox"/> No <input type="checkbox"/> Yes TNF- α -inhibitor <input type="checkbox"/> No <input type="checkbox"/> Yes Selective immunosuppressant <input type="checkbox"/> No <input type="checkbox"/> Yes Purine derivative <input type="checkbox"/> No <input type="checkbox"/> Yes Other: _____
Immunosuppressive- or modulating drugs are an exclusion criterion for participation in the DIST-INFLAME sub-study		

Pre-ICH modified Rankin Scale (mRS) score

- 0 No symptoms
 - 1 Minor symptoms, no limitations
 - 2 Slight disability, no help needed
 - 3 Moderate disability, requires some help but able to walk on assistance
 - 4 Moderate severe disability, not able to walk
 - 5 Severe disability, completely dependent
- Pre-ICH mRS 3-5 is an exclusion criterion, re-evaluate**

Physical examination at baseline – referring center

Referral from other hospital?	<input type="checkbox"/> No <input type="checkbox"/> Yes	If yes, please fill in below
Glasgow Coma Scale - first intra-hospital/at ER in referring center		
Eye	Motor	Verbal
<input type="checkbox"/> 4 - Opens eyes spontaneously	<input type="checkbox"/> 6 - Obeys commands	<input type="checkbox"/> 5 - Oriented/converses normally
<input type="checkbox"/> 3 - Opens eyes in response to voice	<input type="checkbox"/> 5 - Localizes painful stimuli	<input type="checkbox"/> 4 - Confused/disoriented
<input type="checkbox"/> 2 - Opens eyes in resp. to painful stimuli	<input type="checkbox"/> 4 - Flexion/withdrawal to painful stimuli	<input type="checkbox"/> 3 - Utters inappropriate words
<input type="checkbox"/> 1 - Does not open eyes	<input type="checkbox"/> 3 - Abnormal flexion to painful stimuli	<input type="checkbox"/> 2 - Incomprehensible sounds
	<input type="checkbox"/> 2 - Extension to painful stimuli	<input type="checkbox"/> 1 - Makes no sounds
	<input type="checkbox"/> 1 - Makes no movements	

Vital parameters – first intra-hospital/at ER in referring center

Systolic blood pressure _____ mm Hg Diastolic blood pressure _____ mm Hg

Physical examination at baseline – neurosurgical center

Glasgow Coma Scale - first intra-hospital/at ER in neurosurgical center		
Eye	Motor	Verbal
<input type="checkbox"/> 4 - Opens eyes spontaneously	<input type="checkbox"/> 6 - Obeys commands	<input type="checkbox"/> 5 - Oriented/converses normally
<input type="checkbox"/> 3 - Opens eyes in response to voice	<input type="checkbox"/> 5 - Localizes painful stimuli	<input type="checkbox"/> 4 - Confused/disoriented
<input type="checkbox"/> 2 - Opens eyes in resp. to painful stimuli	<input type="checkbox"/> 4 - Flexion/withdrawal to painful stimuli	<input type="checkbox"/> 3 - Utters inappropriate words
<input type="checkbox"/> 1 - Does not open eyes	<input type="checkbox"/> 3 - Abnormal flexion to painful stimuli	<input type="checkbox"/> 2 - Incomprehensible sounds
	<input type="checkbox"/> 2 - Extension to painful stimuli	<input type="checkbox"/> 1 - Makes no sounds
	<input type="checkbox"/> 1 - Makes no movements	

Vital parameters – first intra-hospital/at ER in neurosurgical center

Round numbers except for body temp (1 decimal)

Systolic blood pressure _____ mm Hg Diastolic blood pressure _____ mm Hg
 Heart rate _____ /min Body temperature _____ °C
 Height _____ cm Weight _____ kg



NIHSS at baseline – neurosurgical center

<p>1A. Level of consciousness (LOC)</p> <p><input type="checkbox"/> 0 – Alert</p> <p><input type="checkbox"/> 1 – Not alert, but arousable</p> <p><input type="checkbox"/> 2 – Not alert, requires repeated stimulation</p> <p><input type="checkbox"/> 3 – Comatose</p>	<p>1B. LOC Questions</p> <p><input type="checkbox"/> 0 – Answers both questions correctly</p> <p><input type="checkbox"/> 1 – Answers one question correctly</p> <p><input type="checkbox"/> 2 – Answers neither questions correctly</p>
<p>1C. LOC Commands</p> <p><input type="checkbox"/> 0 – Performs both tasks correctly</p> <p><input type="checkbox"/> 1 – Performs one task correctly</p> <p><input type="checkbox"/> 2 – Performs neither tasks correctly</p>	<p>2. Best gaze</p> <p><input type="checkbox"/> 0 – Normal</p> <p><input type="checkbox"/> 1 – Partial gaze palsy</p> <p><input type="checkbox"/> 2 – Forced deviation</p>
<p>3. Visual</p> <p><input type="checkbox"/> 0 – No visual loss</p> <p><input type="checkbox"/> 1 – Partial hemianopia</p> <p><input type="checkbox"/> 2 – Complete hemianopia</p> <p><input type="checkbox"/> 3 – Bilateral hemianopia</p>	<p>4. Facial palsy</p> <p><input type="checkbox"/> 0 – Normal</p> <p><input type="checkbox"/> 1 – Minor paralysis</p> <p><input type="checkbox"/> 2 – Partial paralysis</p> <p><input type="checkbox"/> 3 – Complete paralysis</p>
<p>5A. Motor left arm</p> <p><input type="checkbox"/> 0 – No drift</p> <p><input type="checkbox"/> 1 – Drift</p> <p><input type="checkbox"/> 2 – Some effort against gravity</p> <p><input type="checkbox"/> 3 – No effort against gravity</p> <p><input type="checkbox"/> 4 – No movement</p> <p><input type="checkbox"/> 9 – Untestable, explain reason: _____</p>	<p>5B. Motor right arm</p> <p><input type="checkbox"/> 0 – No drift</p> <p><input type="checkbox"/> 1 – Drift</p> <p><input type="checkbox"/> 2 – Some effort against gravity</p> <p><input type="checkbox"/> 3 – No effort against gravity</p> <p><input type="checkbox"/> 4 – No movement</p> <p><input type="checkbox"/> 9 – Untestable, explain reason: _____</p>
<p>6A. Motor left leg</p> <p><input type="checkbox"/> 0 – No drift</p> <p><input type="checkbox"/> 1 – Drift</p> <p><input type="checkbox"/> 2 – Some effort against gravity</p> <p><input type="checkbox"/> 3 – No effort against gravity</p> <p><input type="checkbox"/> 4 – No movement</p> <p><input type="checkbox"/> 9 – Untestable, explain reason: _____</p>	<p>6B. Motor right leg</p> <p><input type="checkbox"/> 0 – No drift</p> <p><input type="checkbox"/> 1 – Drift</p> <p><input type="checkbox"/> 2 – Some effort against gravity</p> <p><input type="checkbox"/> 3 – No effort against gravity</p> <p><input type="checkbox"/> 4 – No movement</p> <p><input type="checkbox"/> 9 – Untestable, explain reason: _____</p>
<p>7. Limb ataxia</p> <p><input type="checkbox"/> 0 – Absent</p> <p><input type="checkbox"/> 1 – Present in one limb</p> <p><input type="checkbox"/> 2 – Present in two limbs</p> <p><input type="checkbox"/> 9 – Untestable, explain reason: _____</p>	<p>8. Sensory</p> <p><input type="checkbox"/> 0 – Normal</p> <p><input type="checkbox"/> 1 – Mild to moderate sensory loss</p> <p><input type="checkbox"/> 2 – Severe or total sensory loss</p>
<p>9. Best language</p> <p><input type="checkbox"/> 0 – No aphasia (normal)</p> <p><input type="checkbox"/> 1 – Mild to moderate aphasia</p> <p><input type="checkbox"/> 2 – Severe aphasia</p> <p><input type="checkbox"/> 3 – Mute, global aphasia</p>	<p>10. Dysarthria</p> <p><input type="checkbox"/> 0 – Normal</p> <p><input type="checkbox"/> 1 – Mild to moderate dysarthria</p> <p><input type="checkbox"/> 2 – Severe dysarthria, anarthria, mute</p> <p><input type="checkbox"/> 9 – Intubated, or other, explain: _____</p>
<p>11. Extinction and inattention</p> <p><input type="checkbox"/> 0 – No abnormality</p> <p><input type="checkbox"/> 1 – Inattention or extinction to one sensory modality</p> <p><input type="checkbox"/> 2 – Profound hemi-inattention or extinction to more than one modality</p>	<p>(modalities: visual/tactile/auditory/spatial/personal)</p>

Laboratory results at baseline *Round numbers, except for INR, hemoglobin and glucose (1 decimal)*

Coagulation:		Date & time INR (1 st): ___/___/___ :__	
INR (1 st)	___ . __	If yes:	
Correction for VKA	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> NA	INR (after correction):	___ . __
		Date & time INR (after correction):	___/___/___ :__
Thrombocyte count	_____ *10 ⁹ /L	PT*	_____ sec
APTT*	_____ sec		
Other laboratory results:			
Hemoglobin	___ . __ mmol/L	Leukocyte count	_____ *10 ⁹ /L
Neutrophil count*	_____ *10 ⁹ /L	CRP	_____ mg/L
Serum glucose	___ . __ mmol/L	ASAT	_____ U/L
ALAT	_____ U/L	Alkaline phosphatase	_____ U/L
Bilirubin (total)*	_____ µmol/L	Serum creatinine	_____ umol/L
e-GFR	_____ ml/min/1.73m ²		

* If available



Study number:

Date of inclusion: ___/___/___

Imaging at baseline

Round numbers

Non-contrast CT (NCCT):

Multiple NCCTs performed at baseline? No Yes *e.g., in referring and neurosurgical center*

Date NCCT: ___/___/___ *Enter data for most recent NCCT prior to randomization*

Time NCCT: ___:___

Supratentorial location of hemorrhage No Yes **Infratentorial is an exclusion criterion, re-evaluate**

Specify: Deep No Yes

Lobar No Yes

Uncertain No Yes

ICH-volume (supratentorial) _____ mL *ABC/2 score*

Intraventricular hemorrhage No Yes

CT angiography (CTA) / CT perfusion (CTP):

CT angiography performed? No Yes *date & time of CTA: ___/___/___ ___:___*

CT perfusion performed? No Yes *date & time of CTP: ___/___/___ ___:___*

Acute treatment at baseline (medication)

Hypertension treatment:

Intravenous treatment of hypertension No Yes: *Specify:*

Intravenous labetalol treatment No Yes

Other: _____

Anticoagulant/coagulopathy reversal agents:

Vitamin K No Yes *time of administration: ___:___*

4-factor prothrombin complex concentrate No Yes *time of administration: ___:___*

Idarucizumab No Yes *time of administration: ___:___*

Other coagulation reversal agent No Yes: *Specify: _____*

time of administration: ___:___

Intracranial pressure lowering drugs:

Hypertonic saline No Yes *time of administration: ___:___*

Mannitol No Yes *time of administration: ___:___*

Treatment limitations at admission

Any combination of these strategies is possible*

Do-not-resuscitate No Yes

Withholding endotracheal intubation No Yes

Withholding intensive care admission No Yes

Withholding other treatments that may prolong life No Yes *(e.g. antibiotics, blood transfusion)*

Withholding food and fluids No Yes

Palliation with morphine No Yes

Palliation with benzodiazepine No Yes

Withdrawal of care No Yes *(discontinuation of life-prolonging treatments, e.g. mechanical ventilation, vasopressor medications)*

*** Participants in the DIST must have an active treatment strategy at admission (to prevent treatment bias)**

CONTRAST biobank blood samples at baseline

Did you take a CONTRAST biobank study blood sample after randomization? No Yes

(S)AE Check at baseline

Did the patient experience one or more (serious) adverse event(s)? No Yes **(if Yes, please complete (S)AE form(s))**



Study number:

Date of inclusion: ___/___/___

SURGERY CRF

Name first surgeon	_____	_____
Name second surgeon	_____	_____
Date arrival in operating room	___/___/___	Time arrival in operating room ___:___
Date start anesthesia	___/___/___	Time start anesthesia ___:___

Procedure

Date start intervention (first incision)	___/___/___	Time start intervention (first incision)	___:___
Date end intervention (skin closure)	___/___/___	Time end intervention (skin closure)	___:___
Surgery performed in a hybrid OR	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown		
Device for ICH removal used	<input type="checkbox"/> Artemis® 2.8 mm (Penumbra Inc.) <input type="checkbox"/> Artemis® 2.1 mm (Penumbra Inc.) <input type="checkbox"/> Other: _____		
Neuro-navigation used	<input type="checkbox"/> Brainlab <input type="checkbox"/> Medtronic (StealthStation™)		
Endoscope used	<input type="checkbox"/> LOTTA® (Karl Storz) <input type="checkbox"/> MINOP® (B Braun)		
Irrigation solution used	<input type="checkbox"/> Lactated Ringer's <input type="checkbox"/> Sterofundin <input type="checkbox"/> Other: _____	Estimated amount of irrigation solution used	_____ mL
Number of cannisters used	_____ cannisters		
Conversion to craniotomy	<input type="checkbox"/> No <input type="checkbox"/> Yes		
Endoscopic clot appearance	<input type="checkbox"/> Liquefied clot <input type="checkbox"/> Both liquefied and fibrous clot <input type="checkbox"/> Fibrous clot		
Active bleeding during surgery	<input type="checkbox"/> No <input type="checkbox"/> Yes: Specify: Focal bleeding <input type="checkbox"/> No <input type="checkbox"/> Yes Diffuse bleeding <input type="checkbox"/> No <input type="checkbox"/> Yes	If Yes, specify treatment:	<input type="checkbox"/> Bleeding control by irrigation only <input type="checkbox"/> Bleeding control by electrocautery <input type="checkbox"/> Bleeding control by adjunct hemostatic agent (Floseal®)
Estimated percentage ICH volume reduction	_____ %		
External ventricular drain (EVD) placement	<input type="checkbox"/> No <input type="checkbox"/> Yes		
Surgery resumed or restarted after residual hemorrhage on post-operative control NCCT?	<input type="checkbox"/> No <input type="checkbox"/> Yes		
Per-procedural complications	<input type="checkbox"/> No <input type="checkbox"/> Yes:	If Yes, please fill out (SAE form and specify:	Seizure(s) <input type="checkbox"/> No <input type="checkbox"/> Yes Hemodynamic instability <input type="checkbox"/> No <input type="checkbox"/> Yes Device deficiency <input type="checkbox"/> No <input type="checkbox"/> Yes Other: _____
Lowest blood pressure during surgery (blood pressure during induction and termination of anesthesia excluded)			
Systolic blood pressure _____ mm Hg	Diastolic blood pressure _____ mm Hg		
Highest blood pressure during surgery (blood pressure during induction and termination of anesthesia excluded)			
Systolic blood pressure _____ mm Hg	Diastolic blood pressure _____ mm Hg		

Perioperative medication administration

Anticoagulant/coagulopathy reversal agents:

Platelet transfusion	<input type="checkbox"/> No <input type="checkbox"/> Yes:	time of administration: ___:___
Tranexamic acid	<input type="checkbox"/> No <input type="checkbox"/> Yes:	time of administration: ___:___
Desmopressin (DDAVP®)	<input type="checkbox"/> No <input type="checkbox"/> Yes:	time of administration: ___:___
Other (e.g. erythrocyte transfusion, fibrinogen, fresh frozen plasma)	<input type="checkbox"/> No <input type="checkbox"/> Yes:	Specify: _____ time of administration: ___:___

Intracranial pressure lowering drugs:

Hypertonic saline	<input type="checkbox"/> No <input type="checkbox"/> Yes:	time of administration: ___:___
Mannitol	<input type="checkbox"/> No <input type="checkbox"/> Yes:	time of administration: ___:___
Dexamethasone	<input type="checkbox"/> No <input type="checkbox"/> Yes:	time of administration: ___:___ Dosage ____ . ____ mg

NB: Check whether given by anesthesiologist at induction of anesthesia

Other study procedures

Did you perform a non-contrast CT-scan directly after surgery?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Did you collect a hematoma aspirate sample for the CONTRAST Biobank? (DIST-INFLAME sub-study only)	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> NA

(S)AE Check after surgery

Did the patient experience one or more (serious) adverse (device) event(s) during surgery?	<input type="checkbox"/> No <input type="checkbox"/> Yes (if yes, please complete (S)AE form(s))
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Study number:

Date of inclusion: ___/___/___

CLINICAL FOLLOW UP CRF

24 hours follow-up

Vital parameters at 1, 6, 12 and 24 hours

Vital parameters at 1 hour after arrival in ER neurosurgical center:		<i>Round numbers</i>
Systolic blood pressure	_____ mm Hg	Diastolic blood pressure _____ mm Hg
Heart rate	_____ /min	

Vital parameters at 6 hours:		<i>Round numbers</i>
Systolic blood pressure	_____ mm Hg	Diastolic blood pressure _____ mm Hg
Heart rate	_____ /min	

Vital parameters at 12 hours:		<i>Round numbers</i>
Systolic blood pressure	_____ mm Hg	Diastolic blood pressure _____ mm Hg
Heart rate	_____ /min	

Vital parameters at 24 hours:		<i>Round numbers</i>
Systolic blood pressure	_____ mm Hg	Diastolic blood pressure _____ mm Hg
Heart rate	_____ /min	

Treatment limitations at 24 hours

Any combination of these strategies is possible

Did the treatment limitations at 24 hours change compared to baseline?	<input type="checkbox"/> No <input type="checkbox"/> Yes: if Yes, please fill out below
Do-not-resuscitate	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding endotracheal intubation	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding intensive care admission	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding other treatments that may prolong life	<input type="checkbox"/> No <input type="checkbox"/> Yes (e.g. antibiotics, blood transfusion)
Withholding food and fluids	<input type="checkbox"/> No <input type="checkbox"/> Yes
Palliation with morphine	<input type="checkbox"/> No <input type="checkbox"/> Yes
Palliation with benzodiazepine	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withdrawal of care	<input type="checkbox"/> No <input type="checkbox"/> Yes (discontinuation of life-prolonging treatments, e.g. mechanical ventilation, vasopressor medications)

Location of the patient at 24 hours	<input type="checkbox"/> 0 - ICU <input type="checkbox"/> 1 - Medium care <input type="checkbox"/> 2 - Stroke Unit <input type="checkbox"/> 3 - General ward
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Neuroimaging at 24 hours (± 6 hours)

Did you perform a non-contrast CT-scan at 24 hours?	<input type="checkbox"/> No <input type="checkbox"/> Yes
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(S)AE Check at 24 hours

Did the patient experience one or more (serious) adverse event(s)?	<input type="checkbox"/> No <input type="checkbox"/> Yes (if Yes, please complete (S)AE form(s))
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Study number:

Date of inclusion: ___/___/___

Day 3 (± 12 hours) follow-up (DIST-INFLAME sub-study only)

Inclusion in the DIST-INFLAME sub-study

Is the patient included in the DIST-INFLAME sub-study? No Yes: **if Yes, please fill in information below**

Vital parameters at day 3 (± 12 hours)

Date of examination: ___/___/___

Vital parameters at day 3:		Round numbers
Systolic blood pressure	_____ mm Hg	Diastolic blood pressure _____ mm Hg
Heart rate	_____ /min	

DIST-INFLAME sub-study blood sample at day 3 (± 12 hours)

Did you take a DIST-INFLAME sub-study blood sample at day 3? No Yes

Study number:

Date of inclusion: ___/___/___

Day 6 ± 1 day follow-up (or discharge, if earlier)

Vital parameters at day 6 ± 1 day

Date of examination: ___/___/___

Round numbers

Vital parameters at 6 ± 1 days (or discharge if earlier):

Systolic blood pressure _____ mm Hg
Heart rate _____ /min

Diastolic blood pressure _____ mm Hg

NIHSS at day 6 ± 1 day (or discharge if earlier)

Date of examination: ___/___/___

1A Level of consciousness (LOC)

- 0 – Alert
- 1 – Not alert, but arousable
- 2 – Not alert, requires repeated stimulation
- 3 – Comatose

1B LOC Questions

- 0 – Answers both questions correctly
- 1 – Answers one question correctly
- 2 – Answers neither questions correctly

1C LOC Commands

- 0 – Performs both tasks correctly
- 1 – Performs one task correctly
- 2 – Performs neither tasks correctly

2 Best gaze

- 0 – Normal
- 1 – Partial gaze palsy
- 2 – Forced deviation

3 Visual

- 0 – No visual loss
- 1 – Partial hemianopia
- 2 – Complete hemianopia
- 3 – Bilateral hemianopia

4 Facial palsy

- 0 – Normal
- 1 – Minor paralysis
- 2 – Partial paralysis
- 3 – Complete paralysis

5A Motor left arm

- 0 – No drift
- 1 – Drift
- 2 – Some effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- 9 – Untestable, explain reason: _____

5B Motor right arm

- 0 – No drift
- 1 – Drift
- 2 – Some effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- 9 – Untestable, explain reason: _____

6A Motor left leg

- 0 – No drift
- 1 – Drift
- 2 – Some effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- 9 – Untestable, explain reason: _____

6B Motor right leg

- 0 – No drift
- 1 – Drift
- 2 – Some effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- 9 – Untestable, explain reason: _____

7 Limb ataxia

- 0 – Absent
- 1 – Present in one limb
- 2 – Present in two limbs
- 9 – Untestable, explain reason: _____

8 Sensory

- 0 – Normal
- 1 – Mild to moderate sensory loss
- 2 – Severe or total sensory loss

9 Best language

- 0 – No aphasia (normal)
- 1 – Mild to moderate aphasia
- 2 – Severe aphasia
- 3 – Mute, global aphasia

10 Dysarthria

- 0 – Normal
- 1 – Mild to moderate dysarthria
- 2 – Severe dysarthria, anarthria, mute
- 9 – Intubated, or other, explain: _____

11 Extinction and inattention

- 0 – No abnormality
- 1 – Inattention or extinction to one sensory modality
- 2 – Profound hemi-inattention or extinction to more than one modality

(modalities: visual/tactile/auditory/spatial/personal)

Study number:

Date of inclusion: ___/___/___

EQ-5D-5L at day 6 ± 1 day (or discharge if earlier)

Date of examination: ___/___/___

1. Mobility

- 1 – I have no problems in walking about
- 2 – I have slight problems in walking about
- 3 – I have moderate problems in walking about
- 4 – I have severe problems in walking about
- 5 – I am unable to walk about

3. Usual activities

- 1 – I have no problems doing my usual activities
- 2 – I have slight problems doing my usual activities
- 3 – I have moderate problems doing my usual activities
- 4 – I have severe problems doing my usual activities
- 5 – I am unable to do my usual activities

5. Anxiety/depression

- 1 – I am not anxious or depressed
- 2 – I am slightly anxious or depressed
- 3 – I am moderately anxious or depressed
- 4 – I am severely anxious or depressed
- 5 – I am extremely anxious or depressed

2. Self-care

- 1 – I have no problems washing or dressing myself
- 2 – I have slight problems washing or dressing myself
- 3 – I have moderate problems washing or dressing myself
- 4 – I have severe problems washing or dressing myself
- 5 – I am unable to wash and dress myself

4. Pain/discomfort

- 1 – I have no pain or discomfort
- 2 – I have slight pain or discomfort
- 3 – I have moderate pain or discomfort
- 4 – I have severe pain or discomfort
- 5 – I have extreme pain or discomfort

EQ-VAS

Reported health today (0-100):

EQ-5D-5L completed by

patient proxy

Treatment limitations at day 6 ± 1 day (or discharge if earlier)

Date of assessment: ___/___/___

Any combination of these strategies is possible

Did the treatment limitations at day 6 ± 1 day change compared to 24 hours?

No Yes: **if Yes, please fill out below**

Do-not-resuscitate

No Yes

Withholding endotracheal intubation

No Yes

Withholding intensive care admission

No Yes

Withholding other treatments that may prolong life

No Yes (e.g. antibiotics, blood transfusion)

Withholding food and fluids

No Yes

Palliation with morphine

No Yes

Palliation with benzodiazepine

No Yes

Withdrawal of care

No Yes (discontinuation of life-prolonging treatments, e.g. mechanical ventilation, vasopressor medications)

Location of the patient at day 6 ± 1 day

- 0 - ICU
- 1 - Medium care
- 2 - Stroke Unit
- 3 - General ward

Neuroimaging at day 6 ± 1 day (or discharge if earlier)

Did you perform a non-contrast CT-scan at day 6 ± 1 day (or discharge if earlier)? No Yes

DIST-INFLAME sub-study blood sample at day 6 ± 1 day (or discharge if earlier)

Did you take a DIST-INFLAME sub-study blood sample at day 6 ± 1 day? (DIST-INFLAME sub-study only) No Yes NA

(S)AE Check at day 6 ± 1 day (or discharge if earlier)

Did the patient experience one or more (serious) adverse event(s)? No Yes (if Yes, please complete (S)AE form(s))

Discharge – Neurosurgical center

Neuroimaging

Any additional neuroimaging performed during hospital stay? (excluding study neuroimaging) No Yes

Interventions and diagnoses during hospital stay

Neurological deterioration (NIHSS ≥ 4) due to ICH expansion No Yes: **fill out SAE form**

Intracranial infection No Yes: **fill out SAE form**

Seizure(s) No Yes: **fill out SAE form**

Intubation (excluding intubation for study surgery) No Yes: **fill out SAE form**

Surgical intervention (excluding study surgery) No Yes: **fill out SAE form**

If yes, specify:

External ventricular drain (EVD) No Yes Date of intervention: ___/___/___

Craniotomy with hematoma evacuation No Yes Date of intervention: ___/___/___

Hemicraniectomy with hematoma evacuation No Yes Date of intervention: ___/___/___

Hemicraniectomy without hematoma evacuation No Yes Date of intervention: ___/___/___

ICP monitoring No Yes Date of intervention: ___/___/___

Burr hole(s) No Yes Date of intervention: ___/___/___

Other: _____ Date of intervention: ___/___/___

Other major medical intervention No Yes: **fill out SAE form and describe:** _____

Antihypertensive medication during hospital stay

Any type of antihypertensive medication No Yes:

If applicable:

Intravenous labetalol No Yes Start date ___/___/___ Stop date ___/___/___

Intravenous nicardipine No Yes Start date ___/___/___ Stop date ___/___/___

ACE inhibitor No Yes Start date ___/___/___ Stop date ___/___/___

Angiotensin II receptor antagonist No Yes Start date ___/___/___ Stop date ___/___/___

Beta blocker No Yes Start date ___/___/___ Stop date ___/___/___

Calcium channel blocker No Yes Start date ___/___/___ Stop date ___/___/___

Diuretic No Yes Start date ___/___/___ Stop date ___/___/___

Other (intravenous or oral): _____ Start date ___/___/___ Stop date ___/___/___

Platelet inhibitor(s) during hospital stay

Any type of platelet inhibitor No Yes:

If applicable:

Acetylsalicylic acid/carbasalate calcium No Yes Start date ___/___/___ Stop date ___/___/___

Clopidogrel No Yes Start date ___/___/___ Stop date ___/___/___

Dipyridamole No Yes Start date ___/___/___ Stop date ___/___/___

Ticagrelor No Yes Start date ___/___/___ Stop date ___/___/___

Other: _____ Start date ___/___/___ Stop date ___/___/___

Direct oral anticoagulant (DOAC) during hospital stay

Any type of DOAC No Yes:

If applicable:

Apixaban (Eliquis®) No Yes Start date ___/___/___ Stop date ___/___/___

Dabigatran (Pradaxa®) No Yes Start date ___/___/___ Stop date ___/___/___

Edoxaban (Lixiana®) No Yes Start date ___/___/___ Stop date ___/___/___

Rivaroxaban (Xarelto®) No Yes Start date ___/___/___ Stop date ___/___/___

Vitamin K antagonist(s) during hospital stay

Any type of vitamin K antagonist No Yes:

If applicable:

Acenocoumarol No Yes Start date ___/___/___ Stop date ___/___/___

Phenprocoumon No Yes Start date ___/___/___ Stop date ___/___/___

Heparin during hospital stay

Any type of heparin No Yes:

If applicable:

Prophylactic heparin No Yes Start date ___/___/___ Stop date ___/___/___

Therapeutic heparin No Yes Start date ___/___/___ Stop date ___/___/___

Admission

Was the patient admitted to the:

<ul style="list-style-type: none"> - ICU <input type="checkbox"/> No <input type="checkbox"/> Yes - Medium care <input type="checkbox"/> No <input type="checkbox"/> Yes - Stroke Unit <input type="checkbox"/> No <input type="checkbox"/> Yes - General ward (not stroke unit) <input type="checkbox"/> No <input type="checkbox"/> Yes 	<p>Total number of days in:</p> <ul style="list-style-type: none"> - ICU _____ - Medium care _____ - Stroke Unit _____ - General ward _____
---	---



Study number:

Date of inclusion: ___/___/___

Discharge

Was the patient discharged No Yes
Date of discharge (dead or alive) ___/___/___

Discharge destination:

- 0** - Patient died (**please fill out SAE form**)
- 1** - Home
- 2** - Other hospital (**transfer; please fill out transfer CRF**)
- 3** - Geriatric rehabilitation
- 4** - Nursing home long stay
- 5** - Rehabilitation center
- 6** - Other: _____

Name of discharge destination: _____

Treatment limitations at discharge – Neurosurgical center

Any combination of these strategies is possible

Did the treatment limitations at discharge change compared to day 6 ± 1 day? No Yes: **if Yes, please fill out below**

- | | |
|--|---|
| Do-not-resuscitate | <input type="checkbox"/> No <input type="checkbox"/> Yes |
| Withholding endotracheal intubation | <input type="checkbox"/> No <input type="checkbox"/> Yes |
| Withholding intensive care admission | <input type="checkbox"/> No <input type="checkbox"/> Yes |
| Withholding other treatments that may prolong life | <input type="checkbox"/> No <input type="checkbox"/> Yes <i>(e.g. antibiotics, blood transfusion)</i> |
| Withholding food and fluids | <input type="checkbox"/> No <input type="checkbox"/> Yes |
| Palliation with morphine | <input type="checkbox"/> No <input type="checkbox"/> Yes |
| Palliation with benzodiazepine | <input type="checkbox"/> No <input type="checkbox"/> Yes |
| Withdrawal of care | <input type="checkbox"/> No <input type="checkbox"/> Yes <i>(discontinuation of life-prolonging treatments, e.g. mechanical ventilation, vasopressor medications)</i> |

(S)AE Check at discharge – Neurosurgical center

Did the patient experience one or more (serious) adverse event(s) during hospital stay? No Yes (**if Yes, please complete (S)AE form(s)**)

Study number:

Date of inclusion: ___/___/___

Dutch ICH Surgery Trial (DIST): SERIOUS ADVERSE EVENTS (SAE) CRF

SAE number: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10

General information

Name investigator: _____ Signature investigator: _____

Date of report: ___/___/___ DD/MM/YYYY

Description of SAE (in Dutch or English):

Date of SAE onset

Date: ___/___/___ DD/MM/YYYY

Neuroimaging

Was there neuroimaging performed for this SAE? No Yes

(Serious) Adverse Event category, please choose one:

- 0 – Results in death
- 1 – Life threatening (at the time of event)
- 2 – Requires prolonged hospitalization
- 3 – Results in persistent or significant disability or incapacity
- 4 – Other, please specify: _____
- 5 – Not listed above (i.e. not a **serious** adverse event)

SAE expected?

An SAE is 'expected' if this is one of the known side effects of the study treatment or one of the common (potentially) serious complications after ICH.

If No: please report the unexpected SAE within 24 hours.

No Yes

Select most likely cause for SAE, please choose one:

- 0 – Intracerebral hemorrhage progression
- 1 – Intracerebral hemorrhage (other location, symptomatic)
- 2 – Ischemic stroke
- 3 – Subdural/epidural hematoma
- 4 – Hydrocephalus
- 5 – Surgical device deficiency
- 6 – Extracranial hemorrhage (e.g. gastro-intestinal)
- 7 – Cardiac ischemia
- 8 – Allergic reaction
- 9 – Pneumonia
- 10- Intracranial infection
- 11- Postoperative site infection
- 12- Other infection: _____
- 13- Deep venous thrombosis or pulmonary embolism
- 14- Seizure(s)
- 15- Other: _____

Was there another cause for SAE, you may choose multiple

- No Yes:
- 0 – Intracerebral hemorrhage progression
 - 1 – Intracerebral hemorrhage (other location, symptomatic)
 - 2 – Ischemic stroke
 - 3 – Subdural/epidural hematoma
 - 4 – Hydrocephalus
 - 5 – Surgical device deficiency
 - 6 – Extracranial hemorrhage (e.g. gastro-intestinal)
 - 7 – Cardiac ischemia
 - 8 – Allergic reaction
 - 9 – Pneumonia
 - 10- Intracranial infection
 - 11- Postoperative site infection
 - 12- Other infection: _____
 - 13- Deep venous thrombosis or pulmonary embolism
 - 14- Seizure(s)
 - 15- Other: _____

Relationship with the study procedures

- 0 - None
- 1 - Unlikely
- 2 - Possible
- 3 - Probable
- 4 - Definite

Actions regarding study participation

- 0 - None
- 1 - Interrupted
- 2 - Withdrawn
- 3 - Other, please specify: _____

Outcome

- 0 - Resolved without sequela(e) date: ___/___/___ DD/MM/YYYY
- 1 - Resolved with sequela(e) date: ___/___/___ DD/MM/YYYY and describe sequela(e): _____
- 2 - Ongoing (pending)
- 3 - Death date: ___/___/___ DD/MM/YYYY

Additional (S)AE forms are available on the website: dutch-ich.nl

Study number:

Date of inclusion: ___/___/___

Wat is een SAE?

SAE is de afkorting van Serious Adverse Event. Een SAE is een ongewenst medisch voorval bij een patiënt of proefpersoon dat niet noodzakelijk een oorzakelijk verband heeft met het onderzoek en dat:

- dodelijk is, en/of
- levensgevaar oplevert voor de proefpersoon, en/of
- opname in een ziekenhuis of verlenging van de opname noodzakelijk maakt, en/of
- blijvende of significante invaliditeit of arbeidsongeschiktheid veroorzaakt, en/of
- zich uit in een aangeboren afwijking of misvorming

Een patiënt kan meerdere SAE's hebben gedurende de follow-up periode. Het terugplaatsen van een botlap is een SAE, omdat de patiënt opnieuw moet worden opgenomen in het ziekenhuis. Mocht de patiënt een verkeersongeluk krijgen en worden opgenomen vanwege een operatie van bijvoorbeeld de heup, dan is het wederom een SAE. De dood is per definitie een SAE, ook al is de doodsoorzaak niet gerelateerd aan de studie/de bloeding. Hieronder geven we enkele voorbeelden van SAE's.

Study number:

Date of inclusion: 10 / 09 / 2022

Dutch ICH Surgery Trial (DIST): SERIOUS ADVERSE EVENTS (SAE) CRF

SAE number: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10

General information

Name investigator: Dr. A. Janssen

Signature investigator: _____

Date of report: 12 / 09 / 2022

Description of SAE (in Dutch or English):

72-year-old female patient with a deep intracerebral hemorrhage with intraventricular extension, allocated to the control arm. After admission, the patient experienced gradual impairment of consciousness. CT-cerebrum revealed progressive ventricular enlargement, with no evidence of hematoma expansion on day 1. A right frontal EVD was inserted, which demonstrated a high opening pressure. After EVD insertion, a significant improvement in the patient's clinical condition was noted.

Date of SAE onset

Date: 11 / 09 / 2022

Neuroimaging

Was there neuroimaging performed for this SAE? No Yes

(Serious) Adverse Event category, please choose one:

- 0 - Results in death
- 1 - Life threatening (at the time of event)
- 2 - Requires prolonged hospitalization
- 3 - Results in persistent or significant disability or incapacity
- 4 - Other, please specify: _____
- 5 - Not listed above (i.e. not a serious adverse event)

SAE expected?

An SAE is 'expected' if this is one of the known side effects of the study treatment or one of the common (potential) serious complications after ICH.
If No: please report the unexpected SAE within 24 hours.
 No Yes

Select most likely cause for SAE, please choose one:

- 0 - Intracerebral hemorrhage progression
- 1 - Intracerebral hemorrhage (other location, symptomatic)
- 2 - Ischemic stroke
- 3 - Subdural/epidural hematoma
- 4 - Hydrocephalus
- 5 - Surgical device deficiency
- 6 - Extracranial hemorrhage (e.g. gastro-intestinal)
- 7 - Cardiac ischemia
- 8 - Allergic reaction
- 9 - Pneumonia
- 10 - Intracranial infection
- 11 - Postoperative site infection
- 12 - Other infection: _____
- 13 - Deep venous thrombosis or pulmonary embolism
- 14 - Seizure(s)
- 15 - Other: _____

Was there another cause for SAE, you may choose multiple

- No Yes:
 - 0 - Intracerebral hemorrhage progression
 - 1 - Intracerebral hemorrhage (other location, symptomatic)
 - 2 - Ischemic stroke
 - 3 - Subdural/epidural hematoma
 - 4 - Hydrocephalus
 - 5 - Surgical device deficiency
 - 6 - Extracranial hemorrhage (e.g. gastro-intestinal)
 - 7 - Cardiac ischemia
 - 8 - Allergic reaction
 - 9 - Pneumonia
 - 10 - Intracranial infection
 - 11 - Postoperative site infection
 - 12 - Other infection: _____
 - 13 - Deep venous thrombosis or pulmonary embolism
 - 14 - Seizure(s)
 - 15 - Other: _____

Relationship with the study procedures

- 0 - None
- 1 - Unlikely
- 2 - Possible
- 3 - Probable
- 4 - Definite

Actions regarding study participation

- 0 - None
- 1 - Interrupted
- 2 - Withdrawn
- 3 - Other, please specify: _____

Outcome

- 0 - Resolved without sequela(e) date: ___/___/___ DD/MM/YYYY
- 1 - Resolved with sequela(e) date: ___/___/___ DD/MM/YYYY and describe sequela(e): _____
- 2 - Ongoing (pending) date: ___/___/___ DD/MM/YYYY
- 3 - Death date: ___/___/___ DD/MM/YYYY

Additional (S)AE forms are available on the website: dutch-ich.nl



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Study number:

Date of inclusion: 06 / 10 / 2022

Dutch ICH Surgery Trial (DIST): SERIOUS ADVERSE EVENTS (SAE) CRF

SAE number: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10

General information

Name investigator: Dr. B. de Vries

Signature investigator: _____

Date of report: 15 / 10 / 2022

Description of SAE (in Dutch or English):

81-year-old male patient with a lobar intracerebral hemorrhage, allocated to the surgical arm. Surgery was without complications. Patient developed fever (T 39.2 °C) on day 5. Laboratory results showed elevated inflammatory markers. X-thorax showed right lower lobe infiltrate suggestive of pneumonia, for which treatment with amoxicillin/clavulanic acid was started. This led to prolonged hospital stay.

Date of SAE onset

Date: 11 / 10 / 2022

Neuroimaging

Was there neuroimaging performed for this SAE? No Yes

(Serious) Adverse Event category, please choose one:

- 0 - Results in death
- 1 - Life threatening (at the time of event)
- 2 - Requires prolonged hospitalization
- 3 - Results in persistent or significant disability or incapacity
- 4 - Other, please specify: _____
- 5 - Not listed above (i.e. not a serious adverse event)

SAE expected?

An SAE is 'expected' if this is one of the known side effects of the study treatment or one of the common (potential) serious complications after ICH.
If No: please report the unexpected SAE within 24 hours.
 No Yes

Select most likely cause for SAE, please choose one:

- 0 - Intracerebral hemorrhage progression
- 1 - Intracerebral hemorrhage (other location, symptomatic)
- 2 - Ischemic stroke
- 3 - Subdural/epidural hematoma
- 4 - Hydrocephalus
- 5 - Surgical device deficiency
- 6 - Extracranial hemorrhage (e.g. gastro-intestinal)
- 7 - Cardiac ischemia
- 8 - Allergic reaction
- 9 - Pneumonia
- 10 - Intracranial infection
- 11 - Postoperative site infection
- 12 - Other infection: _____
- 13 - Deep venous thrombosis or pulmonary embolism
- 14 - Seizure(s)
- 15 - Other: _____

Was there another cause for SAE, you may choose multiple

- No Yes:
 - 0 - Intracerebral hemorrhage progression
 - 1 - Intracerebral hemorrhage (other location, symptomatic)
 - 2 - Ischemic stroke
 - 3 - Subdural/epidural hematoma
 - 4 - Hydrocephalus
 - 5 - Surgical device deficiency
 - 6 - Extracranial hemorrhage (e.g. gastro-intestinal)
 - 7 - Cardiac ischemia
 - 8 - Allergic reaction
 - 9 - Pneumonia
 - 10 - Intracranial infection
 - 11 - Postoperative site infection
 - 12 - Other infection: _____
 - 13 - Deep venous thrombosis or pulmonary embolism
 - 14 - Seizure(s)
 - 15 - Other: _____

Relationship with the study procedures

- 0 - None
- 1 - Unlikely
- 2 - Possible
- 3 - Probable
- 4 - Definite

Actions regarding study participation

- 0 - None
- 1 - Interrupted
- 2 - Withdrawn
- 3 - Other, please specify: _____

Outcome

- 0 - Resolved without sequela(e) date: ___/___/___ DD/MM/YYYY
- 1 - Resolved with sequela(e) date: ___/___/___ DD/MM/YYYY and describe sequela(e): _____
- 2 - Ongoing (pending) date: ___/___/___ DD/MM/YYYY
- 3 - Death date: ___/___/___ DD/MM/YYYY

Additional (S)AE forms are available on the website: dutch-ich.nl



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Study number:

Date of inclusion: ___/___/___

CRFs Second hospital (transfer)

Day 3 (± 12 hours) follow-up (DIST-INFLAME sub-study only)

Inclusion in the DIST-INFLAME sub-study

Is the patient included in the DIST-INFLAME sub-study? No Yes: **if Yes, please fill in information below**

Vital parameters at day 3 (± 12 hours) – Second hospital (transfer) Date of examination: ___/___/___

Vital parameters at day 3:		<i>Round numbers</i>
Systolic blood pressure	_____ mm Hg	Diastolic blood pressure _____ mm Hg
Heart rate	_____ /min	

DIST-INFLAME sub-study blood sample at day 3 (± 12 hours) – Second hospital (transfer)

Did you take a DIST-INFLAME sub-study blood sample at day 3? No Yes

Day 6 ± 1 day follow-up (or discharge, if earlier)

Vital parameters at 6 ± 1 day (or discharge, if earlier) – Second hospital (transfer)

Date of examination: ___/___/___

Vital parameters at 6 ± 1 days (or discharge if earlier):		Round numbers
Systolic blood pressure _____ mm Hg	Diastolic blood pressure _____ mm Hg	
Heart rate _____ /min		

NIHSS at day 6 ± 1 day (or discharge, if earlier) – Second hospital (transfer)

Date of examination: ___/___/___

1A Level of consciousness (LOC) <input type="checkbox"/> 0 – Alert <input type="checkbox"/> 1 – Not alert, but arousable <input type="checkbox"/> 2 – Not alert, requires repeated stimulation <input type="checkbox"/> 3 – Comatose	1B LOC Questions <input type="checkbox"/> 0 – Answers both questions correctly <input type="checkbox"/> 1 – Answers one question correctly <input type="checkbox"/> 2 – Answers neither questions correctly
1C LOC Commands <input type="checkbox"/> 0 – Performs both tasks correctly <input type="checkbox"/> 1 – Performs one task correctly <input type="checkbox"/> 2 – Performs neither tasks correctly	2 Best gaze <input type="checkbox"/> 0 – Normal <input type="checkbox"/> 1 – Partial gaze palsy <input type="checkbox"/> 2 – Forced deviation
3 Visual <input type="checkbox"/> 0 – No visual loss <input type="checkbox"/> 1 – Partial hemianopia <input type="checkbox"/> 2 – Complete hemianopia <input type="checkbox"/> 3 – Bilateral hemianopia	4 Facial palsy <input type="checkbox"/> 0 – Normal <input type="checkbox"/> 1 – Minor paralysis <input type="checkbox"/> 2 – Partial paralysis <input type="checkbox"/> 3 – Complete paralysis
5A Motor left arm <input type="checkbox"/> 0 – No drift <input type="checkbox"/> 1 – Drift <input type="checkbox"/> 2 – Some effort against gravity <input type="checkbox"/> 3 – No effort against gravity <input type="checkbox"/> 4 – No movement <input type="checkbox"/> 9 – Untestable, explain reason: _____	5B Motor right arm <input type="checkbox"/> 0 – No drift <input type="checkbox"/> 1 – Drift <input type="checkbox"/> 2 – Some effort against gravity <input type="checkbox"/> 3 – No effort against gravity <input type="checkbox"/> 4 – No movement <input type="checkbox"/> 9 – Untestable, explain reason: _____
6A Motor left leg <input type="checkbox"/> 0 – No drift <input type="checkbox"/> 1 – Drift <input type="checkbox"/> 2 – Some effort against gravity <input type="checkbox"/> 3 – No effort against gravity <input type="checkbox"/> 4 – No movement <input type="checkbox"/> 9 – Untestable, explain reason: _____	6B Motor right leg <input type="checkbox"/> 0 – No drift <input type="checkbox"/> 1 – Drift <input type="checkbox"/> 2 – Some effort against gravity <input type="checkbox"/> 3 – No effort against gravity <input type="checkbox"/> 4 – No movement <input type="checkbox"/> 9 – Untestable, explain reason: _____
7 Limb ataxia <input type="checkbox"/> 0 – Absent <input type="checkbox"/> 1 – Present in one limb <input type="checkbox"/> 2 – Present in two limbs <input type="checkbox"/> 9 – Untestable, explain reason: _____	8 Sensory <input type="checkbox"/> 0 – Normal <input type="checkbox"/> 1 – Mild to moderate sensory loss <input type="checkbox"/> 2 – Severe or total sensory loss
9 Best language <input type="checkbox"/> 0 – No aphasia (normal) <input type="checkbox"/> 1 – Mild to moderate aphasia <input type="checkbox"/> 2 – Severe aphasia <input type="checkbox"/> 3 – Mute, global aphasia	10 Dysarthria <input type="checkbox"/> 0 – Normal <input type="checkbox"/> 1 – Mild to moderate dysarthria <input type="checkbox"/> 2 – Severe dysarthria, anarthria, mute <input type="checkbox"/> 9 – Intubated, or other, explain: _____
11 Extinction and inattention <input type="checkbox"/> 0 – No abnormality <input type="checkbox"/> 1 – Inattention or extinction to one sensory modality <input type="checkbox"/> 2 – Profound hemi-inattention or extinction to more than one modality	<i>(modalities: visual/tactile/auditory/spatial/personal)</i>

EQ-5D-5L at day 6 ± 1 day (or discharge if earlier) – Second hospital (transfer)

Date of examination: ___/___/___

1. Mobility <input type="checkbox"/> 1 – I have no problems in walking about <input type="checkbox"/> 2 – I have slight problems in walking about <input type="checkbox"/> 3 – I have moderate problems in walking about <input type="checkbox"/> 4 – I have severe problems in walking about <input type="checkbox"/> 5 – I am unable to walk about	2. Self-care <input type="checkbox"/> 1 – I have no problems washing or dressing myself <input type="checkbox"/> 2 – I have slight problems washing or dressing myself <input type="checkbox"/> 3 – I have moderate problems washing or dressing myself <input type="checkbox"/> 4 – I have severe problems washing or dressing myself <input type="checkbox"/> 5 – I am unable to wash and dress myself
3. Usual activities <input type="checkbox"/> 1 – I have no problems doing my usual activities <input type="checkbox"/> 2 – I have slight problems doing my usual activities <input type="checkbox"/> 3 – I have moderate problems doing my usual activities <input type="checkbox"/> 4 – I have severe problems doing my usual activities <input type="checkbox"/> 5 – I am unable to do my usual activities	4. Pain/discomfort <input type="checkbox"/> 1 – I have no pain or discomfort <input type="checkbox"/> 2 – I have slight pain or discomfort <input type="checkbox"/> 3 – I have moderate pain or discomfort <input type="checkbox"/> 4 – I have severe pain or discomfort <input type="checkbox"/> 5 – I have extreme pain or discomfort
5. Anxiety/depression <input type="checkbox"/> 1 – I am not anxious or depressed <input type="checkbox"/> 2 – I am slightly anxious or depressed <input type="checkbox"/> 3 – I am moderately anxious or depressed <input type="checkbox"/> 4 – I am severely anxious or depressed <input type="checkbox"/> 5 – I am extremely anxious or depressed	EQ-VAS Reported health today (0-100): _____
EQ-5D-5L completed by	<input type="checkbox"/> patient <input type="checkbox"/> proxy

Treatment limitations at day 6 ± 1 day (or discharge if earlier) – Second hospital (transfer)

Date of examination: ___/___/___

Any combination of these strategies is possible	
Did the treatment limitations at day 6 ± 1 day change compared to 24 hours?	<input type="checkbox"/> No <input type="checkbox"/> Yes: if Yes, please fill out below
Do-not-resuscitate	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding endotracheal intubation	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding intensive care admission	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding other treatments that may prolong life	<input type="checkbox"/> No <input type="checkbox"/> Yes (e.g. antibiotics, blood transfusion)
Withholding food and fluids	<input type="checkbox"/> No <input type="checkbox"/> Yes
Palliation with morphine	<input type="checkbox"/> No <input type="checkbox"/> Yes
Palliation with benzodiazepine	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withdrawal of care	<input type="checkbox"/> No <input type="checkbox"/> Yes (discontinuation of life-prolonging treatments, e.g. mechanical ventilation, vasopressor medications)
Location of the patient at day 6 ± 1 day	<input type="checkbox"/> 0 - ICU <input type="checkbox"/> 1 - Medium care <input type="checkbox"/> 2 - Stroke Unit <input type="checkbox"/> 3 - General ward

Neuroimaging at day 6 ± 1 day (or discharge if earlier) – Second hospital (transfer)

Did you perform a non-contrast CT-scan at day 6 ± 1 day (or discharge if earlier)?	<input type="checkbox"/> No <input type="checkbox"/> Yes
--	--

DIST-INFLAME sub-study blood sample at day 6 ± 1 day (or discharge if earlier) – Second hospital (transfer)

Did you take a DIST-INFLAME sub-study blood sample at day 6 ± 1 day? (DIST-INFLAME sub-study only)	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> NA
--	--

(S)AE Check at day 6 ± 1 day (or discharge if earlier) – Second hospital (transfer)

Did the patient experience one or more (serious) adverse event(s)?	<input type="checkbox"/> No <input type="checkbox"/> Yes (if Yes, please complete (S)AE form(s))
--	--

Discharge – Second hospital (transfer)

Neuroimaging in second hospital

Was there neuroimaging performed at your center? No Yes

Interventions and diagnoses during hospital stay in second hospital

Neurological deterioration (NIHSS ≥ 4) due to ICH expansion No Yes: **fill out SAE form**

Intracranial infection No Yes: **fill out SAE form**

Seizure(s) No Yes: **fill out SAE form**

Intubation (excluding intubation for study surgery) No Yes: **fill out SAE form**

Surgical intervention (excluding study surgery) No Yes: **fill out SAE form**

If yes, specify:

External ventricular drain (EVD) No Yes Date of intervention: ___/___/___

Craniotomy with hematoma evacuation No Yes Date of intervention: ___/___/___

Hemicraniectomy with hematoma evacuation No Yes Date of intervention: ___/___/___

Hemicraniectomy without hematoma evacuation No Yes Date of intervention: ___/___/___

ICP monitoring No Yes Date of intervention: ___/___/___

Burr hole(s) No Yes Date of intervention: ___/___/___

Other: _____ Date of intervention: ___/___/___

Other major medical intervention No Yes: **fill out SAE form and describe:** _____

Antihypertensive medication during hospital stay in second hospital

Any type of antihypertensive medication No Yes:

If applicable:

Intravenous labetalol No Yes Start date ___/___/___ Stop date ___/___/___

Intravenous nicardipine No Yes Start date ___/___/___ Stop date ___/___/___

ACE inhibitor No Yes Start date ___/___/___ Stop date ___/___/___

Angiotensin II receptor antagonist No Yes Start date ___/___/___ Stop date ___/___/___

Beta blocker No Yes Start date ___/___/___ Stop date ___/___/___

Calcium channel blocker No Yes Start date ___/___/___ Stop date ___/___/___

Diuretic No Yes Start date ___/___/___ Stop date ___/___/___

Other (intravenous or oral): _____ Start date ___/___/___ Stop date ___/___/___

Platelet inhibitor(s) during hospital stay in second hospital

Any type of platelet inhibitor No Yes:

If applicable:

Acetylsalicylic acid/carbasalate calcium No Yes Start date ___/___/___ Stop date ___/___/___

Clopidogrel No Yes Start date ___/___/___ Stop date ___/___/___

Dipyridamole No Yes Start date ___/___/___ Stop date ___/___/___

Ticagrelor No Yes Start date ___/___/___ Stop date ___/___/___

Other: _____ Start date ___/___/___ Stop date ___/___/___

Direct oral anticoagulant (DOAC) during hospital stay in second hospital

Any type of DOAC No Yes:

If applicable:

Apixaban (Eliquis®) No Yes Start date ___/___/___ Stop date ___/___/___

Dabigatran (Pradaxa®) No Yes Start date ___/___/___ Stop date ___/___/___

Edoxaban (Lixiana®) No Yes Start date ___/___/___ Stop date ___/___/___

Rivaroxaban (Xarelto®) No Yes Start date ___/___/___ Stop date ___/___/___

Vitamin K antagonist(s) during hospital stay in second hospital

Any type of vitamin K antagonist No Yes:

If applicable:

Acenocoumarol No Yes Start date ___/___/___ Stop date ___/___/___

Phenprocoumon No Yes Start date ___/___/___ Stop date ___/___/___

Heparin during hospital stay in second hospital

Any type of heparin No Yes:

If applicable:

Prophylactic heparin No Yes Start date ___/___/___ Stop date ___/___/___

Therapeutic heparin No Yes Start date ___/___/___ Stop date ___/___/___

Admission in second hospital

Was the patient admitted to the:

- ICU No Yes
- Medium care No Yes
- Stroke Unit No Yes
- General ward (not stroke unit) No Yes

Total number of days in:

- ICU _____
- Medium care _____
- Stroke Unit _____
- General ward _____

Study number:

Date of inclusion: ___/___/___

Discharge (destination after second hospital)

Was the patient discharged No Yes
Date of discharge (dead or alive) ___/___/___

Discharge destination:

0 - Patient died (**please fill out SAE form**)

1 - Home

2 - Other hospital

3 - Geriatric rehabilitation

4 - Nursing home long stay

5 - Rehabilitation center

6 - Other: _____

Name of discharge destination: _____

Treatment limitations at discharge – Second hospital (transfer)

Any combination of these strategies is possible

Did the treatment limitations at discharge change compared to day 6 ± 1 day? No Yes: **if Yes, please fill out below**

Do-not-resuscitate

No Yes

Withholding endotracheal intubation

No Yes

Withholding intensive care admission

No Yes

Withholding other treatments that may prolong life

No Yes (e.g. antibiotics, blood transfusion)

Withholding food and fluids

No Yes

Palliation with morphine

No Yes

Palliation with benzodiazepine

No Yes

Withdrawal of care

No Yes (discontinuation of life-prolonging treatments, e.g. mechanical ventilation, vasopressor medications)

(S)AE Check at discharge – Second hospital (transfer)

Did the patient experience one or more (serious) adverse event(s) during hospital stay? No Yes (**if Yes, please complete (S)AE form(s)**)

Study number:

Date of inclusion: ___/___/___

Dutch ICH Surgery Trial (DIST): SERIOUS ADVERSE EVENTS (SAE) CRF

SAE number: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10

General information

Name investigator: _____ Signature investigator: _____

Date of report: ___/___/___ DD/MM/YYYY

Description of SAE (in Dutch or English):

Date of SAE onset

Date: ___/___/___ DD/MM/YYYY

Neuroimaging

Was there neuroimaging performed for this SAE? No Yes

(Serious) Adverse Event category, please choose one:

- 0 – Results in death
- 1 – Life threatening (at the time of event)
- 2 – Requires prolonged hospitalization
- 3 – Results in persistent or significant disability or incapacity
- 4 – Other, please specify: _____
- 5 – Not listed above (i.e. not a **serious** adverse event)

SAE expected?

An SAE is 'expected' if this is one of the known side effects of the study treatment or one of the common (potentially) serious complications after ICH.

If No: please report the unexpected SAE within 24 hours.

No Yes

Select most likely cause for SAE, please choose one:

- 0 – Intracerebral hemorrhage progression
- 1 – Intracerebral hemorrhage (other location, symptomatic)
- 2 – Ischemic stroke
- 3 – Subdural/epidural hematoma
- 4 – Hydrocephalus
- 5 – Surgical device deficiency
- 6 – Extracranial hemorrhage (e.g. gastro-intestinal)
- 7 – Cardiac ischemia
- 8 – Allergic reaction
- 9 – Pneumonia
- 10- Intracranial infection
- 11- Postoperative site infection
- 12- Other infection: _____
- 13- Deep venous thrombosis or pulmonary embolism
- 14- Seizure(s)
- 15- Other: _____

Was there another cause for SAE, you may choose multiple

- No Yes:
- 0 – Intracerebral hemorrhage progression
 - 1 – Intracerebral hemorrhage (other location, symptomatic)
 - 2 – Ischemic stroke
 - 3 – Subdural/epidural hematoma
 - 4 – Hydrocephalus
 - 5 – Surgical device deficiency
 - 6 – Extracranial hemorrhage (e.g. gastro-intestinal)
 - 7 – Cardiac ischemia
 - 8 – Allergic reaction
 - 9 – Pneumonia
 - 10- Intracranial infection
 - 11- Postoperative site infection
 - 12- Other infection: _____
 - 13- Deep venous thrombosis or pulmonary embolism
 - 14- Seizure(s)
 - 15- Other: _____

Relationship with the study procedures

- 0 - None
- 1 - Unlikely
- 2 - Possible
- 3 - Probable
- 4 - Definite

Actions regarding study participation

- 0 - None
- 1 - Interrupted
- 2 - Withdrawn
- 3 - Other, please specify: _____

Outcome

- 0 - Resolved without sequela(e) date: ___/___/___ DD/MM/YYYY
- 1 - Resolved with sequela(e) date: ___/___/___ DD/MM/YYYY and describe sequela(e): _____
- 2 - Ongoing (pending)
- 3 - Death date: ___/___/___ DD/MM/YYYY

Additional (S)AE forms are available on the website: dutch-ich.nl

Study number:

Date of inclusion: ___/___/___

Wat is een SAE?

SAE is de afkorting van Serious Adverse Event. Een SAE is een ongewenst medisch voorval bij een patiënt of proefpersoon dat niet noodzakelijk een oorzakelijk verband heeft met het onderzoek en dat:

- dodelijk is, en/of
- levensgevaar oplevert voor de proefpersoon, en/of
- opname in een ziekenhuis of verlenging van de opname noodzakelijk maakt, en/of
- blijvende of significante invaliditeit of arbeidsongeschiktheid veroorzaakt, en/of
- zich uit in een aangeboren afwijking of misvorming

Een patiënt kan meerdere SAE's hebben gedurende de follow-up periode. Het terugplaatsen van een botlap is een SAE, omdat de patiënt opnieuw moet worden opgenomen in het ziekenhuis. Mocht de patiënt een verkeersongeluk krijgen en worden opgenomen vanwege een operatie van bijvoorbeeld de heup, dan is het wederom een SAE. De dood is per definitie een SAE, ook al is de doodsoorzaak niet gerelateerd aan de studie/de bloeding. Hieronder geven we enkele voorbeelden van SAE's.

Study number:

Date of inclusion: 10 / 09 / 2022

Dutch ICH Surgery Trial (DIST): SERIOUS ADVERSE EVENTS (SAE) CRF

SAE number: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10

General information

Name investigator: Dr. A. Janssen

Signature investigator: _____

Date of report: 12 / 09 / 2022

Description of SAE (in Dutch or English):

72-year-old female patient with a deep intracerebral hemorrhage with intraventricular extension, allocated to the control arm. After admission, the patient experienced gradual impairment of consciousness. CT-cerebrum revealed progressive ventricular enlargement, with no evidence of hematoma expansion on day 1. A right frontal EVD was inserted, which demonstrated a high opening pressure. After EVD insertion, a significant improvement in the patient's clinical condition was noted.

Date of SAE onset

Date: 11 / 09 / 2022

Neuroimaging

Was there neuroimaging performed for this SAE? No Yes

(Serious) Adverse Event category, please choose one:

- 0 - Results in death
- 1 - Life threatening (at the time of event)
- 2 - Requires prolonged hospitalization
- 3 - Results in persistent or significant disability or incapacity
- 4 - Other, please specify: _____
- 5 - Not listed above (i.e. not a serious adverse event)

SAE expected?

An SAE is 'expected' if this is one of the known side effects of the study treatment or one of the common (potential) serious complications after ICH.

If No: please report the unexpected SAE within 24 hours.

No Yes

Select most likely cause for SAE, please choose one:

- 0 - Intracerebral hemorrhage progression
- 1 - Intracerebral hemorrhage (other location, symptomatic)
- 2 - Ischemic stroke
- 3 - Subdural/epidural hematoma
- 4 - Hydrocephalus
- 5 - Surgical device deficiency
- 6 - Extracranial hemorrhage (e.g. gastro-intestinal)
- 7 - Cardiac ischemia
- 8 - Allergic reaction
- 9 - Pneumonia
- 10 - Intracranial infection
- 11 - Postoperative site infection
- 12 - Other infection: _____
- 13 - Deep venous thrombosis or pulmonary embolism
- 14 - Seizure(s)
- 15 - Other: _____

Was there another cause for SAE, you may choose multiple

- No Yes:
 - 0 - Intracerebral hemorrhage progression
 - 1 - Intracerebral hemorrhage (other location, symptomatic)
 - 2 - Ischemic stroke
 - 3 - Subdural/epidural hematoma
 - 4 - Hydrocephalus
 - 5 - Surgical device deficiency
 - 6 - Extracranial hemorrhage (e.g. gastro-intestinal)
 - 7 - Cardiac ischemia
 - 8 - Allergic reaction
 - 9 - Pneumonia
 - 10 - Intracranial infection
 - 11 - Postoperative site infection
 - 12 - Other infection: _____
 - 13 - Deep venous thrombosis or pulmonary embolism
 - 14 - Seizure(s)
 - 15 - Other: _____

Relationship with the study procedures

- 0 - None
- 1 - Unlikely
- 2 - Possible
- 3 - Probable
- 4 - Definite

Actions regarding study participation

- 0 - None
- 1 - Interrupted
- 2 - Withdrawn
- 3 - Other, please specify: _____

Outcome

- 0 - Resolved without sequela(e) date: ___/___/___ DD/MM/YYYY
- 1 - Resolved with sequela(e) date: ___/___/___ DD/MM/YYYY and describe sequela(e): _____
- 2 - Ongoing (pending) date: ___/___/___ DD/MM/YYYY
- 3 - Death date: ___/___/___ DD/MM/YYYY

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Study number:

Date of inclusion: 06 / 10 / 2022

Dutch ICH Surgery Trial (DIST): SERIOUS ADVERSE EVENTS (SAE) CRF

SAE number: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10

General information

Name investigator: Dr. B. de Vries

Signature investigator: _____

Date of report: 15 / 10 / 2022

Description of SAE (in Dutch or English):

81-year-old male patient with a lobar intracerebral hemorrhage, allocated to the surgical arm. Surgery was without complications. Patient developed fever (T 39.2 °C) on day 5. Laboratory results showed elevated inflammatory markers. X-thorax showed right lower lobe infiltrate suggestive of pneumonia, for which treatment with amoxicillin/clavulanic acid was started. This led to prolonged hospital stay.

Date of SAE onset

Date: 11 / 10 / 2022

Neuroimaging

Was there neuroimaging performed for this SAE? No Yes

(Serious) Adverse Event category, please choose one:

- 0 - Results in death
- 1 - Life threatening (at the time of event)
- 2 - Requires prolonged hospitalization
- 3 - Results in persistent or significant disability or incapacity
- 4 - Other, please specify: _____
- 5 - Not listed above (i.e. not a serious adverse event)

SAE expected?

An SAE is 'expected' if this is one of the known side effects of the study treatment or one of the common (potential) serious complications after ICH.

If No: please report the unexpected SAE within 24 hours.

No Yes

Select most likely cause for SAE, please choose one:

- 0 - Intracerebral hemorrhage progression
- 1 - Intracerebral hemorrhage (other location, symptomatic)
- 2 - Ischemic stroke
- 3 - Subdural/epidural hematoma
- 4 - Hydrocephalus
- 5 - Surgical device deficiency
- 6 - Extracranial hemorrhage (e.g. gastro-intestinal)
- 7 - Cardiac ischemia
- 8 - Allergic reaction
- 9 - Pneumonia
- 10 - Intracranial infection
- 11 - Postoperative site infection
- 12 - Other infection: _____
- 13 - Deep venous thrombosis or pulmonary embolism
- 14 - Seizure(s)
- 15 - Other: _____

Was there another cause for SAE, you may choose multiple

- No Yes:
 - 0 - Intracerebral hemorrhage progression
 - 1 - Intracerebral hemorrhage (other location, symptomatic)
 - 2 - Ischemic stroke
 - 3 - Subdural/epidural hematoma
 - 4 - Hydrocephalus
 - 5 - Surgical device deficiency
 - 6 - Extracranial hemorrhage (e.g. gastro-intestinal)
 - 7 - Cardiac ischemia
 - 8 - Allergic reaction
 - 9 - Pneumonia
 - 10 - Intracranial infection
 - 11 - Postoperative site infection
 - 12 - Other infection: _____
 - 13 - Deep venous thrombosis or pulmonary embolism
 - 14 - Seizure(s)
 - 15 - Other: _____

Relationship with the study procedures

- 0 - None
- 1 - Unlikely
- 2 - Possible
- 3 - Probable
- 4 - Definite

Actions regarding study participation

- 0 - None
- 1 - Interrupted
- 2 - Withdrawn
- 3 - Other, please specify: _____

Outcome

- 0 - Resolved without sequela(e) date: ___/___/___ DD/MM/YYYY
- 1 - Resolved with sequela(e) date: ___/___/___ DD/MM/YYYY and describe sequela(e): _____
- 2 - Ongoing (pending) date: ___/___/___ DD/MM/YYYY
- 3 - Death date: ___/___/___ DD/MM/YYYY

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