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 1.0, September 2022

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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Study number: _____ Date of inclusion: ____/____/___

BASELINE CRF

Demographics

Ethnicity/race	□ White □ Black or African American □ Asian □ Hispanic or Latino □ Mixed □ Other: _____

Medical history/comorbidities at baseline

Medical history of:		
Atrial fibrillation or flutter	□ No □ Yes	
Chronic heart failure	□ No □ Yes	
Deep venous thrombosis	□ No □ Yes	
Pulmonary embolism	□ No □ Yes	
Diabetes mellitus	□ No □ Yes	*(on treatment for diabetes or 2x fasting glucose >7 mmol/l)*
Hypertension	□ No □ Yes	*(on treatment for hypertension or known with high blood pressure (2x SBP >140 or DBP >90 mm Hg))*
Hypercholesterolemia	□ No □ Yes	*(using lipid-lowering drugs or total cholesterol >6.2 mmol/l)*
Labile INR	□ No □ Yes	*(unstable/high INRs, time in therapeutic range <60%)*
Liver disease	□ No □ Yes:	Specify: Liver cirrhosis □ No □ Yes Other, please specify: _____
Renal disease	□ No □ Yes:	Specify: Dialysis □ No □ Yes Renal transplant □ No □ Yes Other, please specify: _____
Previous intracerebral hemorrhage	□ No □ Yes	
Ischemic stroke	□ No □ Yes	
Transient ischemic attack	□ No □ Yes	
Prior major bleeding	□ No □ Yes	
Predisposition to bleeding	□ No □ Yes	
Mechanical aorta and/or mitral valve replacement	□ No □ Yes	
Myocardial infarction	□ No □ Yes	
Peripheral artery disease	□ No □ Yes	
Premorbid cognitive complaints	□ No □ Yes	
Falls in the past year	□ No □ Yes:	Specify: number of falls _____
Comorbidity influencing mRS	□ No □ Yes:	Specify: _____
Intoxication(s):		
Smoking status	□ Never □ Current □ Stopped < 6 months ago □ Stopped > 6 months ago	
Use of alcohol	□ No □ Yes:	units/week: _____
Use of drugs	□ No □ Yes:	Specify: Amphetamines □ No □ Yes Cannabis □ No □ Yes Cocaine □ No □ Yes GHB □ No □ Yes MDMA (XTC) □ No □ Yes Opiates □ No □ Yes Other: _____
Medication (home) – use of:		
Antihypertensive drug(s)	□ No □ Yes:	Specify: ACE-inhibitor *(e.g. lisinopril, enalapril)* □ No □ Yes Angiotensin II rec antagonist *(e.g. losartan)* □ No □ Yes Beta blocker *(e.g. metoprolol, atenolol)* □ No □ Yes Calcium channel blocker *(e.g. amlodipine)* □ No □ Yes Diuretic *(e.g. furosemide, hydrochlorothiazide)* □ No □ Yes Other: _____

Study number: | Date of inclusion: ____/____/___

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

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? □ No □ Yes **If yes, please fill in below**

Glasgow Coma Scale - first intra-hospital/at ER in referring center

Eye	Motor	Verbal
□ **4** - Opens eyes spontaneously	□ **6** - Obeys commands	□ **5** - Oriented/converses normally
□ **3** - Opens eyes in response to voice	□ **5** - Localizes painful stimuli	□ **4** - Confused/disoriented
□ **2** - Opens eyes in resp. to painful stimuli	□ **4** - Flexion/withdrawal to painful stimuli	□ **3** - Utters inappropriate words
□ **1** - Does not open eyes	□ **3** - Abnormal flexion to painful stimuli	□ **2** - Incomprehensible sounds
	□ **2** - Extension to painful stimuli	□ **1** - Makes no sounds
	□ **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
□ **4** - Opens eyes spontaneously	□ **6** - Obeys commands	□ **5** - Oriented/converses normally
□ **3** - Opens eyes in response to voice	□ **5** - Localizes painful stimuli	□ **4** - Confused/disoriented
□ **2** - Opens eyes in resp. to painful stimuli	□ **4** - Flexion/withdrawal to painful stimuli	□ **3** - Utters inappropriate words
□ **1** - Does not open eyes	□ **3** - Abnormal flexion to painful stimuli	□ **2** - Incomprehensible sounds
	□ **2** - Extension to painful stimuli	□ **1** - Makes no sounds
	□ **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 __ __ . __ ^{0}C
Height _____ cm Weight _____ kg

Study number: _____ Date of inclusion: ____/____/___

NIHSS at baseline – neurosurgical center

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

Laboratory results at baseline

Round numbers, except for INR, hemoglobin and glucose (1 decimal)

Coagulation:					
INR (1st)	__ __ . _		Date & time INR (1st):	__/__/___ __:__	
Correction for VKA	□ No □ Yes □ NA		If yes: INR (after correction): Date & time INR (after correction):	 __ __ . _ __/__/___ __:__	
Thrombocyte count	_____	*10^9/L			
APTT*	_____	sec	PT*	_____	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/1.73m²			

** If available*

Study number: | Date of inclusion: ____/____/___

Imaging at baseline

Round numbers

Non-contrast CT (NCCT) neurosurgical center:		
Date NCCT neurosurgical center	___/___/_____	
Time NCCT neurosurgical center	___:___	
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	□ No □ Yes □ Unknown	
Device for ICH removal used	□ Artemis®, Penumbra Inc. □ Other: _____	
Neuro-navigation used	□ Brainlab □ Medtronic (StealthStation™)	
Endoscope used	□ LOTTA® (Karl Storz) □ MINOP® (B Braun)	
Irrigation solution used	□ Lactated Ringer's □ Sterofundin □ Other: _____	Estimated amount of irrigation solution used _____ mL
Number of cannisters used	_____ cannisters	
Conversion to craniotomy	□ No □ Yes	
Endoscopic clot appearance	□ Liquefied clot □ Both liquefied and fibrous clot □ Fibrous clot	
Active bleeding during surgery	□ No □ Yes:	If Yes, specify treatment:
Specify: Focal bleeding	□ No □ Yes	□ Bleeding control by irrigation only
Diffuse bleeding	□ No □ Yes	□ Bleeding control by electrocautery □ Bleeding control by adjunct hemostatic agent (Floseal®)
Estimated percentage ICH volume reduction		_____%
External ventricular drain (EVD) placement		□ No □ Yes
Surgery resumed or restarted after residual hemorrhage on post-operative control NCCT?		□ No □ Yes
Per-procedural complications	□ No □ Yes:	If Yes, **please fill out (SA)E form** and specify: Seizure(s) □ No □ Yes Hemodynamic instability □ No □ Yes Device deficiency □ No □ 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	□ No □ Yes:	time of administration: ___:___
Tranexamic acid	□ No □ Yes:	time of administration: ___:___
Desmopressin (DDAVP®)	□ No □ Yes:	time of administration: ___:___
Other (e.g. erythrocyte transfusion, fibrinogen, fresh frozen plasma)	□ No □ Yes:	Specify: _____ time of administration: ___:___
Intracranial pressure lowering drugs:		
Hypertonic saline	□ No □ Yes:	time of administration: ___:___
Mannitol	□ No □ Yes:	time of administration: ___:___
Dexamethasone	□ No □ 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?	□ No □ Yes
Did you collect a hematoma aspirate sample for the CONTRAST Biobank? *(DIST-INFLAME sub-study only)*	□ No □ Yes □ NA

(S)AE Check after surgery

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

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:			*Round numbers*
Systolic blood pressure	_____ mm Hg	Diastolic blood pressure	_____ mm Hg
Heart rate	_____ /min		

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

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

Vital parameters at 24 hours:			*Round numbers*
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?	□ 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 24 hours	□ **0** - ICU □ **1** - Medium care □ **2** - Stroke Unit □ **3** - General ward

Neuroimaging at 24 hours (±6 hours)

Did you perform a non-contrast CT-scan at 24 hours?	□ No □ Yes

(S)AE Check at 24 hours

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

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: ___/___/_____

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)

Date of examination: ___/___/_____

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

Study number: | Date of inclusion: ____/____/___

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))**

Study number: | Date of inclusion: ____/____/___

Discharge – Neurosurgical center

Neuroimaging			
Any additional neuroimaging performed during hospital stay? (excluding study neuroimaging)		□ No □ Yes	
Interventions and diagnoses during hospital stay			
Neurological deterioration due to intracerebral hemorrhage 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 __/__/____
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:		Total number of days in:	
- ICU	□ No □ Yes	- ICU	_____
- Medium care	□ No □ Yes	- Medium care	_____
- Stroke Unit	□ No □ Yes	- Stroke Unit	_____
- General ward (not stroke unit)	□ No □ Yes	- General ward	_____

Study number: | Date of inclusion: ____/____/___

Discharge		
Was the patient discharged	□ No □ Yes	Discharge destination:
Date of discharge (dead or alive)	__ /__ /____	□ **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	□ 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 – 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: 20103 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 **x** Yes

(Serious) Adverse Event **category**, please choose one:

□ **0** – Results in death
x 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 **x** 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
x 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

x 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

x 0 - None
□ **1** - Unlikely
□ **2** - Possible
□ **3** - Probable
□ **4** - Definite

Actions regarding study participation

x 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): _____
x 2 - Ongoing (pending)
□ **3** - Death date: __/__/____ DD/MM/YYYY

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

Dutch ICH Surgery Trial CONTRAST Page 1 | Version 1.0 12-09-2022

Study number: 20381 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? **x** No □ Yes

(Serious) Adverse Event **category**, please choose one:

□ **0** – Results in death
□ **1** – Life threatening (at the time of event)
x 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 **x** 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
x 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

x 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
x 1 - Unlikely
□ **2** - Possible
□ **3** - Probable
□ **4** - Definite

Actions regarding study participation

x 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): _____
x 2 - Ongoing (pending)
□ **3** - Death date: __/__/____ DD/MM/YYYY

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

Dutch ICH Surgery Trial CONTRAST Page 1 | Version 1.0 12-09-2022

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:			*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) – Second hospital (transfer)

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

Study number: | Date of inclusion: ____/____/___

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?	□ 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) – Second hospital (transfer)

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) – Second hospital (transfer)

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) – Second hospital (transfer)

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: ____/____/___

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 due to intracerebral hemorrhage 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 __/__/____
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:		Total number of days in:	
- ICU	□ No □ Yes	- ICU	_____
- Medium care	□ No □ Yes	- Medium care	_____
- Stroke Unit	□ No □ Yes	- Stroke Unit	_____
- General ward (not stroke unit)	□ No □ Yes	- General ward	_____

Study number: | Date of inclusion: ____/____/___

Discharge (destination after second hospital)

Was the patient discharged	□ No □ Yes	Discharge destination:
Date of discharge (dead or alive)	__ /__ /____	□ **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: 20103 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 x Yes

(Serious) Adverse Event **category**, please choose one:

□ **0** – Results in death
x **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 x 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
x **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

x 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

x **0** - None
□ **1** - Unlikely
□ **2** - Possible
□ **3** - Probable
□ **4** - Definite

Actions regarding study participation

x **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): _____
x **2** - Ongoing (pending)
□ **3** - Death date: __/__/____ DD/MM/YYYY

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

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Study number: 20381 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? x No □ Yes

(Serious) Adverse Event **category**, please choose one:

□ **0** – Results in death
□ **1** – Life threatening (at the time of event)
x **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 x 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
x **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

x 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
x **1** - Unlikely
□ **2** - Possible
□ **3** - Probable
□ **4** - Definite

Actions regarding study participation

x **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): _____
x **2** - Ongoing (pending)
□ **3** - Death date: __/__/____ DD/MM/YYYY

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