

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):	1	/	

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

Kind regards,

The DIST team

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Study number: BASELINE CRF		Date of inclusion:/
Demographics		
Ethnicity/race	□ White □ Black or African American □ Asian □ Hispanic or Latino □ Mixed □ Other:	
Medical history/com	orbidities 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

Deep venous thrombosis	□ NO □ Yes				
Pulmonary embolism	□ No □ Yes				
Diabetes mellitus	□ No □ Yes	(on treatment for diabetes or	· 2x fasting glucose >7 i	mmol/I)	
Hypertension	⊓ No ⊓ Yes	(on treatment for hypertension			
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Hypercholesterolemia	□ No □ Yes	(using lipid-lowering drugs of	r total cholesterol >6.2 r	mmol/l)	
Labile INR	□ No □ Yes	(unstable/high INRs, time in	therapeutic range <60%	6)	
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	□ No □ Yes				
valve replacement					
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 □ Curre	ent □ Stopped < 6 months	ago 🗆 Stopped > 6	months ago	
Use of alcohol	□ No □ Yes:	units/week:		J	
Use of drugs	□ No □ Yes:	Specify:			
3		Amphetamines	□ No □ Yes		
		Cannabis	□ No □ Yes		
		Cocaine	⊓ No ⊓ Yes		
		GHB	□ No □ Yes		
		MDMA (XTC)	□ No □ Yes		
		Opiates	□ No □ Yes		
		Other:	2		
Medication (home) – use of:		<u> </u>			
Antihypertensive drug(s)	□ No □ Yes:	Specify:			
, and if porton or a diag(o)	40 _ 100.	ACE-inhibitor (e.g. lisino	nnril enalanril)	□ No □ Yes	
		Angiotensin II rec antag		□ No □ Yes	
		Beta blocker (e.g. meto)		□ No □ Yes	
		Calcium channel block		□ No □ Yes	
		Diuretic (e.g. furosemide		□ No □ Yes	
		Other:	,,	2.10 2 100	





Antiplatelet agent(s)	□ No □ Yes:	Specify:		
/ implatolot agoni(o)	- 110 - 100.	Acetylsalicylic acid/carba	salate calcium	□ No □ Yes
		Clopidogrel		□ No □ Yes
		Dipyridamole		□ No □ Yes
		Ticagrelor		□ No □ Yes
\rac{1}{2} \tag{1}	NI V	Other:		
Vitamin K antagonist	□ No □ Yes:	<u>Specify:</u> Acenocoumarol		⊓ No ⊓ Yes
		Phenprocoumon		□ No □ Yes
Direct oral anticoagulant (DOAC)	□ No □ Yes:	Specify:		- 110 - 100
3, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4, 4,		Dabigatran (Pradaxa®)		□ No □ Yes
		Other:		
		Other DOACs (anti-Xa inhibitare an exclusion criterion, re		oxaban, rivaroxaban)
Therapeutic heparin (all types, including LMW)	H) □ No □ Yes	Usage of therapeutic heparis		riterion, re-evaluate.
		Prophylactic heparin is allow	wed.	
NSAID (daily in last 7 days)	□ No □ Yes □ No □ Yes			
Statin Immunosuppressive- or modulating drugs		Specify:		
immunosuppressive- or modulating drugs	□ 140 □ 1C3.	Corticosteroid		⊓ No ⊓ Yes
Immunosuppressive- or modulating drugs are		Interleukin inhibitor		□ No □ Yes
for participation in the DIST-INFLAME sub-stud	ly	Calcineurin inhibitor		□ No □ Yes
		TNF-α-inhibitor		□ No □ Yes
		Selective immunosuppres	ssant	□ No □ Yes
		Purine derivative		□ No □ Yes
		Other:		
	7 50			
Pre-ICH modified Rankin Scale (mRS) score			
□ 0 No symptoms □ 1 Minor symptoms, no limitations				
THE INTROCES VITIDIONES. NO INTITIATIONS				
□ 2 Slight disability, no help needed	p but able to walk on	assistance		
□ 2 Slight disability, no help needed □ 3 Moderate disability, requires some hel □ 4 Moderate severe disability, not able to	walk		3-5 is an exclusion	criterion, re-evaluate
□ 2 Slight disability, no help needed □ 3 Moderate disability, requires some help	walk		3-5 is an exclusion	criterion, re-evaluate
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Study number:



Date of inclusion: ____/___/_

Study number:	
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Data	of inclusion:	/	/
Date	oi illiciusion.	/	/

NIHSS at baseline – neurosurgical ce	nter
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NIHSS at baseline – neurosurgica	l 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 stimulatio	n	□ 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 – Normal □ 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 sensor	y modality	(modalities: visual/tactile/auditory/spatial/pe	rsonal)
□ 2 – Profound hemi-inattention or extinction	n to more than		
one modality			
Laboratory results at baseline		Round numbers, except for INR, hemoglobin and	glucose (1 decimal)
Coagulation:			
INR (1 st)		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:			0 #
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





lmaging at baseline		Round numbers
Non-contrast CT (NCCT):		
Multiple NCCTs performed at baseline?	□ No □ Yes	e.g., in referring and neurosurgical center
Date NCCT/	<i></i>	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 (C		
CT angiography performed?	□ No □ Yes	date & time of CTA:/:
CT perfusion performed?	□ No □ Yes	date & time of CTP://:
Acute treatment at baseline (med Hypertension treatment: Intravenous treatment of hypertension	□ No □ Yes:	Specify: Intravenous labetalol treatment □ No □ Yes Other:
Anticoagulant/coagulopathy reversal ag	ents:	
Vitamin K	□ No □ Yes	time of administration::
4-factor prothrombin complex concentrate	□ No □ Yes	time of administration::
ldarucizumab	□ 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::
Mannitol Treatment limitations at admissions at admissions are combination of these strategies is processed in the combination of these strategies is processed in the combination of t	□ No □ Yes	
Mannitol Treatment limitations at admission of these strategies is proportion to the second contraction of these strategies is proportionally the second contraction of the second contraction contraction of the second contraction co	□ No □ Yes	□ No □ Yes
Mannitol Treatment limitations at admission of these strategies is proportion to the second control of the se	□ No □ Yes	□ No □ Yes
Mannitol Treatment limitations at admission of these strategies is properties to the properties of th	□ No □ Yes On oossible*	□ No □ Yes □ No □ Yes □ No □ Yes
Mannitol Treatment limitations at admission Any combination of these strategies is proportion to the properties of the	□ No □ Yes On oossible*	□ No □ Yes (e.g. antibiotics, blood transfusion)
Treatment limitations at admission Any combination of these strategies is proportion to the properties of the properties	□ No □ Yes On oossible*	□ No □ Yes □ No □ Yes □ No □ Yes
Treatment limitations at admission Any combination of these strategies is properties and the properties of the propertie	□ No □ Yes On oossible*	□ No □ Yes (e.g. antibiotics, blood transfusion) □ No □ Yes
Mannitol Treatment limitations at admissions	□ No □ Yes On oossible*	□ No □ Yes (e.g. antibiotics, blood transfusion) □ No □ Yes (discontinuation of life-prolonging treatments, e.g.
Treatment limitations at admission of these strategies is proposed by the prop	□ No □ Yes On oossible* ong life	□ No □ Yes □ Mo □ Yes □ No □ Yes
Treatment limitations at admissic Any combination of these strategies is p Do-not-resuscitate Withholding endotracheal intubation Withholding intensive care admission Withholding other treatments that may prob Withholding food and fluids Palliation with morphine Palliation with benzodiazepine Withdrawal of care	□ No □ Yes On oossible* ong life	□ No □ Yes □ Mo □ Yes □ No □ Yes
Treatment limitations at admission of these strategies is proposed to the second of the	□ No □ Yes On Possible* Dong life Iteratment strategy	□ No □ Yes □ Mo □ Yes □ No □ Yes
Treatment limitations at admission of these strategies is proposed to the second of the	□ No □ Yes On Possible* Dong life Iteratment strategy	□ No □ Yes □ Mo □ Yes □ No □ Yes
Treatment limitations at admission Any combination of these strategies is proportion to the second and strategies is proportion of these strategies is proportion of the second and strategies is proportion of the second and strategies in the second and second and strategies in the second and	□ No □ Yes On Possible* Dong life Iteratment strategy	□ No □ Yes □ Mo □ Yes □ No □ Yes



Study number:



Date of inclusion: ____/___/__

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 Device for ICH removal used		lno \
Device for ICH removal used	□ Artemis® 2.8 mm (Penumbra□ Artemis® 2.1 mm (Penumbra□ Other:	
Neuro-navigation used	□ Brainlab	
	□ Medtronic (StealthStation™)	
Endoscope used	□ LOTTA® (Karl Storz) □ MINOP® (B Braun)	
Irrigation solution used	□ Lactated Ringer's	Estimated amount of irrigation solution used
	□ Sterofundin□ Other:	mL
Number of cannisters used	cannisters	
Conversion to craniotomy	□ No □ Yes	
Endoscopic clot appearance	□ Liquefied clot	
	□ Both liquefied and fibrous clo□ 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) pla		□ No □ Yes
Surgery resumed or restarted after	r residual hemorrhage on	□ No □ Yes
post-operative control NCCT?		
Per-procedural complications	□ No □ Yes:	If Yes, please fill out (SA)E form and specify:
		Seizure(s)
		Hemodynamic instability No Yes
		Device deficiency No Yes Other:
Lowest blood pressure during s	urgery (blood pressure during induct	ion and termination of anesthesia excluded)
Systolic blood pressure	mm Hg	Diastolic blood pressure mm Hg
	surgery (blood pressure during induc	tion and termination of anesthesia excluded)
Systolic blood pressure	mm Hg	Diastolic blood pressure mm Hg
Perioperative medication a	administration	
Anticoagulant/coagulopathy rev		
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, fib fresh frozen plasma)	rinogen, □ No □ Yes:	Specify:time of administration::
Intracranial pressure lowering d	riide.	time of administration
Hypertonic saline	□ No □ Yes:	time of administration::
Mannitol	□ No □ Yes:	time of administration::
Dexamethasone	□ No □ Yes:	time of administration:: mg
NB: Check whether given by anesthesio	ologist at induction of anesthesia	
Other study procedures		
Did you perform a non-contrast CT		No □ Yes
Did you collect a hematoma aspira		ı No □ Yes □ NA
CONTRAST Biobank? (DIST-INFL	_AME sub-study only)	



(S)AE Check after surgery
Did the patient experience one or more (serious) adverse (device) event(s) during surgery?



 $\ \square$ No $\ \square$ 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

•	<u> </u>		
Vital parameters at 1 hou	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 Heart rate	mm Hg /min	Diastolic blood pressure	mm Hg
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		

Vital parameters at 12 hour	's:		Round numbers
Systolic blood pressure Heart rate	mm Hg /min	Diastolic blood pressure	mm Hg

Vital parameters at 24 h	ours:		Round numbers
Systolic blood pressure	mm Hg	Diastolic blood pressure	mm Hg
Heart rate	/min		

Treatment limitations at 24 hours

Treatment mintations at 24 noars		
Any combination of these strategies is possible		
Did the treatment limitations at 24 hours change compared to	□ No □ Yes: if Yes, please fill out below	
baseline?		
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)

D' 1	N 1 N 2	
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	□ No □ Yes (if Yes, please complete (S)AE form(s))
event(s)?	





Study number:			Date of inclusion:	/
Day 3 (±12 hours) foll	ow-up (DIST-INFLAME	E sub-study o	nly)	
Inclusion in the DIST-IN	FLAME sub-study			
Is the patient included in the D	ST-INFLAME sub-study?	□ No □ Yes:	if Yes, please f	ill in information below
Vital parameters at day	3 (±12 hours)		Date of ex	amination://
Vital parameters at day 3:				Round numbers
Systolic blood pressure	mm Hg	Diastolic blood	oressure	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	□ No □ Yes	
day 3?		





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 (o	r discharge if earlier):		Round numbers
Systolic blood pressure	mm Hg	Diastolic blood pressure	mm Hg
Heart rate	/min		
		D	
NIHSS at day 6 ± 1 day (or		Date of exa	mination://
1A Level of consciousness (LOC	3)	1B LOC Questions	
□ 0 – Alert		□ 0 – Answers both questions corre	
□ 1 – Not alert, but arousable		□ 1 – Answers one question correct	
□ 2 – Not alert, requires repeated	stimulation	□ 2 – Answers neither questions co	rrectly
□ 3 – Comatose			
1C LOC Commands		2 Best gaze	
□ 0 – Performs both tasks correctly	y	□ 0 – Normal	
□ 1 - Performs one task correctly		□ 1 – Partial gaze palsy	
□ 2 – Performs neither tasks corre	ctly	□ 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:6A Motor left leg		9 – Untestable, explain reason: _6B Motor right leg	
□ 0 – No drift		□ 0 – No drift	
□ 1 – No dilit		□ 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, r	nute
□ 3 – Mute, global aphasia		□ 9 – Intubated, or other, explain:	
11 Extinction and inattention			
□ 0 – No abnormality			
□ 1 – Inattention or extinction to or		(modalities: visual/tactile/auditory/s	oatial/personal)
□ 2 – Profound hemi-inattention or	extinction to more than		
one modality			





TO TO The at day C . A day for discharge if continu	Data of examination:
EQ-5D-5L at day 6 ± 1 day (or discharge if earlier	
1. Mobility	2. Self-care
□ 1 – I have no problems in walking about	□ 1 – I have no problems washing or dressing myself
□ 2 – I have slight problems in walking about	□ 2 – I have slight problems washing or dressing myself
□ 3 – I have moderate problems in walking about	□ 3 – I have moderate problems washing or dressing myself
□ 4 – I have severe problems in walking about	□ 4 - I have severe problems washing or dressing myself
□ 5 – I am unable to walk about	□ 5 - I am unable to wash and dress myself
3. Usual activities	4. Pain/discomfort
□ 1 – I have no problems doing my usual activities	□ 1 – I have no pain or discomfort
□ 2 – I have slight problems doing my usual activities	□ 2 − I have slight pain or discomfort
□ 3 – I have moderate problems doing my usual activities	□ 3 − I have moderate pain or discomfort
□ 4 − I have severe problems doing my usual activities	□ 4 − I have severe pain or discomfort
□ 5 – I am unable to do my usual activities	□ 5 − I have extreme pain or discomfort
5. Anxiety/depression	EQ-VAS
□ 1 − I am not anxious or depressed	Reported health today (0-100):
□ 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	4 4
EQ-5D-5L completed by	□ patient □ proxy
Treatment limitations at day 6 ± 1 day (or discha	rge if earlier) Date of assessment:/
	Date of assessment
Any combination of these strategies is possible	- No - Voca if Voc. places fill out below
Did the treatment limitations at day 6 ± 1 day change	□ No □ Yes: if Yes, please fill out below
compared to 24 hours?	- No - Voo
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.
Landing of the matient of day 0 . A day	mechanical ventilation, vasopressor medications)
Location of the patient at day 6 ± 1 day	□ 0 - ICU
	□ 1 - Medium care
	□ 2 - Stroke Unit
	□ 3 - General ward
Nouvelmeding of dought 4 dought discharge if a	arliar)
Neuroimaging at day 6 ± 1 day (or discharge if e	
Did you perform a non-contrast CT-scan at day 6 ± 1 day (or	□ No □ Yes
discharge if earlier)?	
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)	- 140 - 100 - 14/1
O I T day: DIOT IIVI LAWL SUD-Study Utily)	
(S)AE Check at day 6 ± 1 day (or discharge if ear	
Did the patient experience one or more (serious) adverse	□ No □ Yes (if Yes, please complete (S)AE form(s))
event(s)?	



Study number:



Date of inclusion: ____/___/

Study number:	Date of inclusion

Discharge - Neurosurgical center

Neuroimaging			
Any additional neuroimaging performed dur	ing hospital	□ No □ Yes	
stay? (excluding study neuroimaging)			
Interventions and diagnoses during hosp	oital stay		
Neurological deterioration (NIHSS ≥4)	□ No □ Yes:	fill out SAE form	
due to ICH expansion			
Intracranial infection	□ No □ Yes:	fill out SAE form	
Seizure(s)	□ No □ Yes:	fill out SAE form	
Intubation (excluding intubation for study surgery)		fill out SAE form	
Surgical intervention (excluding study surgery)		fill out SAE form	
If yes, specify:	□ 140 □ 1C3.	IIII OUL OAL IOIIII	
External ventricular drain (EVD)	□ No □ Yes	Date of intervention:/_	1
Craniotomy with hematoma evacuation		Date of intervention:/_	
Hemicraniectomy with hematoma	□ No □ Yes	Date of intervention:/_	
	□ NO □ Tes	Date of intervention/_	
evacuation	NI- V	Data of interpretations /	
Hemicraniectomy without hematoma	□ No □ Yes	Date of intervention:/_	
evacuation		-	,
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 des	scribe:
Antihypertensive medication during hos	pital 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):	□ 140 □ 1C3	Start date//	Stop date / /
Platelet inhibitor(s) during hospital stay		Start date//	Stop date//
Any type of platelet inhibitor		□ No □ Yes:	
Any type of platelet inflibitor		□ NO □ Tes.	If applicable:
Acetylsalicylic acid/carbasalate calcium	- No - Voo	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:	h = = = !(=) = (= : .	Start date / /	Stop date / /
Direct oral anticoagulant (DOAC) during	nospitai stay	Na Vas	
Any type of DOAC		□ No □ Yes:	If a wall a ship i
A : 1 (FI: : 0)	NI V	0	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 s	stay		
Any type of vitamin K antagonist		□ No □ Yes:	
			If applicable:
Acenocoumarol	□ No □ Yes	Start date / /	Stop 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:	
- İCU	□ No □ Yes	- ICU	
- Medium care	□ No □ Yes	- Medium care	_
- Stroke Unit	□ No □ Yes	- Stroke Unit	
- General ward (not stroke unit)	□ No □ Yes	 General ward 	
` '			





Discharge		
Was the patient discharged Date of discharge (dead or alive)	□ No □ Yes //	Discharge destination:
		Name of discharge destination:

Date of inclusion: ____/___/

Treatment limitations at discharge – Neurosurgical center

Study number:

Any combination of these strategies is possible	
Did the treatment limitations at discharge change compared	□ No □ Yes: if Yes, please fill out below
to day 6 ± 1 day?	•
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	□ No □ Yes (if Yes, please complete (S)AE form(s))
event(s) during hospital stay?	





|--|

_		
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 inca □ 4 - Other, please specify: □ 5 - Not listed above (i.e. not a serious adverse event)	
Select most likely cause for SAE, please choose one:	Was there another cause for SAE, you may choose multiple
 □ 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: 	□ 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	Actions regarding study participation
 0 - None 1 - Unlikely 2 - Possible 3 - Probable 4 - Definite 	 0 - None 1 - Interrupted 2 - Withdrawn 3 - Other, please specify:
Outcome	DDAMAQQQ
□ 0 - Resolved without sequela(e) date:// □ 1 - Resolved with sequela(e) date:// □ 2 - Ongoing (pending)	DD/MM/YYYY DD/MM/YYYY and describe sequela(e):

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





Study number:	Date of inclusion:	_//.	
, i			

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 Study number: 20381 Date of inclusion: 10 / 09 / 2022 Date of inclusion: 06 / 10 / 2022 **Dutch ICH Surgery Trial (DIST): SERIOUS ADVERSE EVENTS (SAE) CRF** Dutch ICH Surgery Trial (DIST): SERIOUS ADVERSE EVENTS (SAE) CRF SAE number: 1/2/3/4/5/6/7/8/9/10 SAE number: 1/2/3/4/5/6/7/8/9/10 Name investigator: Dr. A. Janssen Name investigator: Dr. B. de Vries Date of report: 12 / 09 / 2022 Date of report: 15 / 10 / 2022 Description of SAE (in Dutch or English): Description of SAE (in Dutch or English): Description of Sec. in Botton of england.

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-Best-pear-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 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. inflammatory markers. X-thorax showed right lower lobe inflitrate 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 Date of SAE onset Date: 11 / 09 / 2022 **Neuroimaging**Was there neuroimaging performed for this SAE? **Neuroimaging**Was there neuroimaging performed for this SAE? (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. (Serious) Adverse Event category, please choose one: SAE expected?

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

If No: please report the unexpected SAE within 24 hours. | (Serious) Adverse Event category, please cnoose 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) | □ No x Yes Select most likely cause for SAE, please choose one: Select most likely cause for SAE, please choose one: Was there another cause for SAE, you may choose multiple x No : Yes: Was there another cause for SAE, you may choose multiple x No n Yes: or Ves:

0 - Intracerebral hemorrhage progression

1 - Intracerebral hemorrhage (other location, symptomatic progression)

2 - Isothermic stroke production of the control O – Intracerebral hemorrhage progression
 1 – Intracerebral hemorrhage (other location, sympti
 2 – Ischemic stroke
 3 – Subdural/epidural hematoma 0 - Intracerebral hemorrhage progression
 1 - Intracerebral hemorrhage (other location, symptomatic)
 2 - Ischemic stroke
 3 - Subdural/lepidural hematoma
 4 - Hydrocephalus 0 – Intracerebral hemorrhage progression
 1 – Intracerebral hemorrhage (other location, symptomatic) 2 – Ischemic stroke 3 – Subdural/epidural hematoma 4 – Hydrocephalus a 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 a - 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 - Seizmed. 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 13- Uner intection:

13- Deep venous thrombosis or pulmonary embolism
14- Selzure(s)

15- Other: □ 12- Orner Intection:
□ 13- Deep venous thrombosis or pulmonary embolism
□ 14- Seizure(s)
□ 15- Other: Relationship with the study procedures x 0 - None Actions regarding study participation x 0 - None Relationship with the study procedures Actions regarding study participation Outcome

0 - Resolved without sequela(e)
1 - Resolved with sequela(e)
2 - Ongoing (pending)
3 - Death

date: _ / _ DD/MMYYYY and describe sequelate. date: __I__I___DD/MM/YYYY date: __I__I___DD/MM/YYYY Additional (S)AE forms are available on the website: dutch-ich.nl Additional (S)AE forms are available on the website: dutch-ich.nl CONTRAST Page 1 | Version 1.0 12-09-2022 CONTRAST Page 1 | Version 1.0 12-09-2022





Study number:			Date of inclusion:/	
CRFs Second hospital (tra	nsfer)			
Day 3 (±12 hours) follow-u	ıp (DIST-INFLAMI	E sub-study o	nly)	
Inclusion in the DIST-INFLAI Is the patient included in the DIST-IN	_	□ No □ Yes:	if Yes, please fill in i	information below
Vital parameters at day 3 (±1	2 hours) – Second	hospital (trans	sfer) Date of examina	ation://
Vital parameters at day 3:				Round numbers
Systolic blood pressure Heart rate	mm Hg /min	Diastolic blood p	oressure	mm Hg

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?

Did you take a DIST-INFLAME sub-study blood sample at law in No in Yes

Did you take a DIST-INFLAME sub-study blood sample at law in No in Yes

Did you take a DIST-INFLAME sub-study blood sample at law in No in Yes

Did you take a DIST-INFLAME sub-study blood sample at law in No in Yes

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Did you take a DIST-INFLAME sub-study blood sample at law in No in Yes

Did you take a DIST-INFLAME sub-study blood sample at law in No in Yes

Did you take a DIST-INFLAME sub-study blood sample at law in No in Yes

Did you take a DIST-INFLAME sub-study blood sample at law in No in Yes

Did you take a DIST-INFLAME sub-study blood sample sub-study blood sample at law in Yes

Did you





Study number:	Date of inclusion:	_//	<u> </u>

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

Vital parameters at 6 ± 1 day (or discharge, if ear	, , , , , , , , , , , , , , , , , , , ,
West and the second sec	Date of examination:/_/
Vital parameters at 6 ± 1 days (or discharge if earlier):	Round numbers
Systolic blood pressure mm Hg Heart rate /min	Diastolic blood pressure mm Hg
NIHSS at day 6 ± 1 day (or discharge, if earlier) -	Second hospital (transfer)
Times at day of a ray (or alcoharge, in carner)	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 □ 3 - Some offert against growity	□ 1 – Drift □ 3 - Some effort against growity
□ 2 - Some effort against gravity□ 3 - No effort against gravity	 □ 2 – Some 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)



one modality



Study number:	Date of inclusion: _	/	_/

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

	Date of examination://
1. Mobility	2. Self-care
 □ 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 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 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 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
□ 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	Reported health today (0-100):
EQ-5D-5L completed by	□ patient □ 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	□ No □ Yes: if Yes, please fill out below
compared to 24 hours?	
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 dischard	ne if earlier)	- Second hospital	(transfer)
Neuronnaying a	aι uay υ 🤉	: I Uay	tui uisciiai t	ae II ealliel)	– Second Hospital	(ualisici <i>)</i>

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

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

No Yes NA

6 ± 1 day? (DIST-INFLAME sub-study only)

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

Did the patient experience one or more (serious) adverse	□ No □ Yes (if Yes, please complete (S)AE form(s))
event(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 hosp	oital stay <u>in se</u>	cond hospital	
Neurological deterioration (NIHSS ≥4)	□ No □ Yes:	fill out SAE form	
due to ICH expansion			
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)		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	□ No □ Yes	Date of intervention:/_	
evacuation	- 110 - 100		-'
Hemicraniectomy without hematoma	□ No □ Yes	Date of intervention:/_	/
evacuation	- 110 - 100	Date of intervention	
ICP monitoring	□ No □ Yes	Date of intervention:/_	1
Burr hole(s)	□ No □ Yes	Date of intervention:/_	_/ /
Other:	□ 140 □ 1 C S	Date of intervention:/_	
Other major medical intervention	□ No □ Yes:		_/ scribe:
Other major medical intervention	□ NO □ 1es.	IIII Out SAE IOIIII and des	scribe
Antihypertensive medication during hos	nital stay in so	cond hospital	
Any type of antihypertensive medication	pilai slay <u>iii se</u>	□ No □ Yes:	
Any type of antinypertensive medication			If applicable:
Intravenous labetalol	⊓ No ⊓ Yes	Start date//	Stop date / /
	□ No □ Yes	Start date//	Stop date / /
Intravenous nicardipine			
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 hos		
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 <u>i</u>	n 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 s			<u> </u>
Any type of vitamin K antagonist		□ No □ Yes:	
7 71			If applicable:
Acenocoumarol	□ No □ Yes	Start date//	
Phenprocoumon	□ No □ Yes	Start date / /	Stop date / / Stop date / /
Heparin during hospital stay in second h			
Any type of heparin		□ No □ Yes:	
7 my typo or riopaim		2.10 2.100.	If applicable:
Prophylactic heparin	□ No □ Yes	Start date / /	Stop date / /
Therapeutic heparin	□ No □ Yes	Start date / /	Stop date / /
Admission in second hospital	- 140 - 169	Start date//	Otop date / /
Was the patient admitted to the:		Total number of days in:	
- ICU	□ No □ Yes	- ICU	
	□ No □ Yes		
- Medium care		- Medium care	
- Stroke Unit	□ No □ Yes □ No □ Yes	- Stroke Unit	
 General ward (not stroke unit) 	⊔ INO ⊔ Tes	 General ward 	





Discharge (destination after second hos	spital)	
Was the patient discharged Date of discharge (dead or alive)	□ No □ Yes //	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:

Date of inclusion: ____/___/

Treatment limitations at discharge – Second hospital (transfer)

Study number:

Any combination of these strategies is possible	
Did the treatment limitations at discharge change compared	□ No □ Yes: if Yes, please fill out below
to day 6 ± 1 day?	
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	□ No □ Yes (if Yes, please complete (S)AE form(s))
event(s) during hospital stay?	





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 inca □ 4 - Other, please specify: □ 5 - Not listed above (i.e. not a serious adverse event)	- No - Voc					
Select most likely cause for SAE, please choose one:	Was there another cause for SAE, you may choose multiple					
 □ 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: 	□ 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	Actions regarding study participation					
 0 - None 1 - Unlikely 2 - Possible 3 - Probable 4 - Definite 	 0 - None 1 - Interrupted 2 - Withdrawn 3 - Other, please specify:					
Outcome	DD/MM/AAAAA					
□ 0 - Resolved without sequela(e) date:// □ 1 - Resolved with sequela(e) date:// □ 2 - Ongoing (pending)	DD/MM/YYYY DD/MM/YYYY and describe sequela(e):					

Additional (S)AE forms are available on the website: $\underline{\text{dutch-ich.nl}}$





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	Study number: 20381	Date of inclusion: 06 / 10 / 2022		
Dutch ICH Surgery Trial (DIST): SERIOUS AD	OVERSE EVENTS (SAE) CRF	Dutch ICH Surgery Trial (DIST): SERIOUS A	DVERSE EVENTS (SAE) CRF		
SAE number: 1/2/3/4/5/6/7/8/9/10		SAE number: 1/2/3/4/5/6/7/8/9/10			
General information		General information			
Name investigator: Dr. A. Janssen Signature investigator:		Name investigator: Dr. B. de Vries Signature investigator:			
Date of report: 12 / 09 / 2022		Date of report: 15 / 10 / 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 of SAE onset			
Date: 11 / 09 / 2022		Date: 11 / 10 / 2022			
Neuroimaging Was there neuroimaging performed for this SAE?	□ No x Yes	Neuroimaging Was there neuroimaging performed for this SAE?	x No D Yes		
(Serious) Adverse Event category, please choose one: 0 - Results in death	SAE expected? An SAE is 'expected' if this is one of the known side effects of the study	(Serious) Adverse Event category, please choose one:	SAE expected? An SAE is 'expected' if this is one of the known side effects of the study		
x 1 – Life threatening (at the time of event)	treatment or one of the common (potentially) serious complications	1 - Life threatening (at the time of event)	treatment or one of the common (potentially) serious complications		
 2 – Requires prolonged hospitalization 	after ICH.	x 2 – Requires prolonged hospitalization	after ICH. If No: please report the unexpected SAE within 24 hours.		
 3 – Results in persistent or significant disability or incapacity 	If No: please report the unexpected SAE within 24 hours.	3 – Results in persistent or significant disability or incapacity	in No. please report the unexpected SAE within 24 hours.		
4 – Other, please specify: 5 – Not listed above (i.e. not a serious adverse event)	□ No x Yes	 4 - Other, please specify: 5 - Not listed above (i.e. not a serious adverse event) 	□ No x Yes		
Select most likely cause for SAE, please choose one:	Was there another cause for SAE, you may choose multiple	Select most likely cause for SAE, please choose one:	Was there another cause for SAE, you may choose multiple		
	x No p Yes:		x No a Yes:		
0 – Intracerebral hemorrhage progression	O – Intracerebral hemorrhage progression	0 – Intracerebral hemorrhage progression	0 – Intracerebral hemorrhage progression		
□ 1 - Intracerebral hemorrhage (other location, symptomatic) □ 2 - Ischemic stroke	 □ 1 – Intracerebral hemorrhage (other location, symptomatic) □ 2 – Ischemic stroke 	 □ 1 - Intracerebral hemorrhage (other location, symptomatic) □ 2 - Ischemic stroke 	 1 – Intracerebral hemorrhage (other location, symptomatic) 2 – Ischemic stroke 		
3 - Subdural/epidural hematoma	□ 3 – Subdural/epidural hematoma	3 - Subdural/epidural hematoma	3 - Subdural/epidural hematoma		
x 4 - Hydrocephalus	4 - Hydrocephalus	□ 4 – Hydrocephalus	□ 4 – Hydrocephalus		
□ 5 – Surgical device deficiency	□ 5 – Surgical device deficiency	□ 5 – Surgical device deficiency	□ 5 – Surgical device deficiency		
□ 6 - Extracranial hemorrhage (e.g. gastro-intestinal)	□ 6 – Extracranial hemorrhage (e.g. gastro-intestinal)	 6 – Extracranial hemorrhage (e.g. gastro-intestinal) 7 – Cardiac ischemia 	6 - Extracranial hemorrhage (e.g. gastro-intestinal)		
□ 7 - Cardiac ischemia □ 8 - Allergic reaction	□ 7 - Cardiac ischemia □ 8 - Allergic reaction	8 - Allergic reaction	7 - Cardiac ischemia 8 - Allergic reaction		
9 - Pneumonia	g 9 – Pneumonia	x 9 – Pneumonia	9 – Pneumonia		
□ 10- Intracranial infection	□ 10- Intracranial infection	□ 10- Intracranial infection	□ 10- Intracranial infection		
11- Postoperative site infection	□ 11- Postoperative site infection	11- Postoperative site infection	11- Postoperative site infection		
12- Other infection: 13- Deep venous thrombosis or pulmonary embolism	12- Other infection: 13- Deep venous thrombosis or pulmonary embolism	12- Other infection: 13- Deep venous thrombosis or pulmonary embolism	12- Other infection: 13- Deep venous thrombosis or pulmonary embolism		
□ 14- Seizure(s)	□ 14- Seizure(s)	□ 14- Seizure(s)	□ 14- Seizure(s)		
n 15- Other:	□ 15- Other:	□ 15- Other:	□ 15- Other:		
Relationship with the study procedures	Actions regarding study participation	Relationship with the study procedures	Actions regarding study participation		
x 0 - None	x 0 - None	□ 0 - None	x 0 - None		
□ 1 - Unlikely □ 2 - Possible	1 - Interrupted 2 - Withdrawn	x 1 - Unlikely 2 - Possible	1 - Interrupted 2 - Withdrawn		
3 - Probable	3 - Other, please specify:	3 - Probable	3 - Other, please specify:		
□ 4 - Definite	a - outer, preuse speeny.	4 - Definite	o - otioi, preado specify.		
Outcome		Outcome			
O - Resolved without sequela(e) date: /_ /_ DD/MM/Y		O - Resolved without sequela(e) date: _ / _ / DD/MM/YYYY			
 1 - Resolved with sequela(e) date:I DD/MM/Y x 2 - Ongoing (pending) 	YYY and describe sequela(e):	a 1 - Resolved with sequela(e) date:IIDD/MM/YYYY and describe sequela(e): x 2 - Ongoing (pending)			
3 - Death date:II DD/MM/Y	YYY	a 3 - Death date:II DD/MM/Y	YYY		
Additional (S)AE forms are available on the website: dutch-ich.n	1	Additional (S)AE forms are available on the website: dutch-ich.	<u>ni</u>		
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