

**Early minimally invasive image guided endoscopic evacuation of  
intracerebral haemorrhage: a randomised controlled trial**

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Date: \_\_\_\_\_

Study ID (USB-XXX):USB-\_\_\_\_\_

Location ID: \_\_\_\_\_

PI: PD Dr. med. J. Soleman

Co-PIs: Prof. Dr. med. R. Guzman

Prof. Dr. med. Urs Fischer

Dr. med. Tim Hallenberger

Version 1.2

09.10.2023

## **V1: Screening and baseline: up to 24 hours after symptom onset**

### **Study inclusion**

Inclusion criteria met	<input type="checkbox"/> yes	<input type="checkbox"/> no	
Informed consent received	<input type="checkbox"/> yes	<input type="checkbox"/> no	
Oral informed consent	<input type="checkbox"/> yes	<input type="checkbox"/> no	<b>If yes, date</b> ____/____/____
Consent given by	<input type="checkbox"/> Patient <input type="checkbox"/> Relative <input type="checkbox"/> Legal guardian <input type="checkbox"/> independent physician		
Written informed consent	<input type="checkbox"/> yes	<input type="checkbox"/> no	<b>If yes, date</b> ____/____/____
Consent given by	<input type="checkbox"/> Patient <input type="checkbox"/> Relative <input type="checkbox"/> Legal guardian <input type="checkbox"/> independent physician		

### **Randomisation**

Randomisation date	____/____/____
Randomisation to:	<input type="checkbox"/> Endoscopic evacuation <input type="checkbox"/> medical treatment
Study ID	_____

### **Baseline demographic data**

Sex	<input type="checkbox"/> male	<input type="checkbox"/> female
Ethnicity	<input type="checkbox"/> Caucasian <input type="checkbox"/> Hispanic <input type="checkbox"/> Arabic <input type="checkbox"/> Asian <input type="checkbox"/> African <input type="checkbox"/> Unknown	<input type="checkbox"/> not assessed
Age (years)	_____	

**Baseline medical history (multiple answers possible)**

Previous medical history (multiple answers possible)	<input type="checkbox"/> Myocardial infarction	<input type="checkbox"/> Cerebral ischemia
	<input type="checkbox"/> Mechanical heart valve	<input type="checkbox"/> TIA
	<input type="checkbox"/> Peripheral artery disease	<input type="checkbox"/> previous ICH
	<input type="checkbox"/> Arterial hypertension	<input type="checkbox"/> Diabetes mellitus Type I
	<input type="checkbox"/> Atrial fibrillation	<input type="checkbox"/> Diabetes mellitus Type II
	<input type="checkbox"/> Chronic heart failure	<input type="checkbox"/> Epilepsy
	<input type="checkbox"/> Deep venous thrombosis	<input type="checkbox"/> Dementia
	<input type="checkbox"/> Pulmonary embolism	<input type="checkbox"/> Congenital defects
	<input type="checkbox"/> Liver disease	<input type="checkbox"/> No comorbidities
	<input type="checkbox"/> Renal disease	<input type="checkbox"/> Other: _____
	<input type="checkbox"/> History of tumor	

Previous medication (multiple answers possible)	<input type="checkbox"/> Acetylsalicylic acid	<input type="checkbox"/> Angiotensin II receptor antagonists
	<input type="checkbox"/> Clopidogrel	<input type="checkbox"/> Betablockers
	<input type="checkbox"/> Ticagrelor	<input type="checkbox"/> Diuretics
	<input type="checkbox"/> Prasugrel	<input type="checkbox"/> NSAID
	<input type="checkbox"/> Vitamin K Antagonists	<input type="checkbox"/> Statins
	<input type="checkbox"/> Rivaroxaban	<input type="checkbox"/> Therapeutic heparin
	<input type="checkbox"/> Apixaban	<input type="checkbox"/> Antipsychotics
	<input type="checkbox"/> Dabigatran	<input type="checkbox"/> Antiepileptics
	<input type="checkbox"/> Fondoparinoux	<input type="checkbox"/> Any pain medication
	<input type="checkbox"/> Edoxaban	<input type="checkbox"/> Unknown
	<input type="checkbox"/> Calcium channel blockers	<input type="checkbox"/> No medication
	<input type="checkbox"/> ACE Inhibitors	<input type="checkbox"/> Other: _____

**Baseline radiology**

Location haemorrhage (multiple answers possible)	<input type="checkbox"/> deep	<input type="checkbox"/> right
	<input type="checkbox"/> lobar	<input type="checkbox"/> left
	<input type="checkbox"/> uncertain	<input type="checkbox"/> both sides
ICH volume (abc/2)	_____ mL	
ICH volume volumetry (cm <sup>3</sup> )	_____ cm <sup>3</sup>	
Intraventricular haemorrhage	<input type="checkbox"/> yes	<input type="checkbox"/> no
Stability scan performed	<input type="checkbox"/> yes	<input type="checkbox"/> no
CTA performed	<input type="checkbox"/> yes	<input type="checkbox"/> no

**Baseline clinical examination**

Blood pressure (SBP/DBP; mmHg)	_____ / _____	
Heart rate (bpm)	_____	
Body temperature (°C)	_____	
Height (cm)	_____	
Weight (kg)	_____	
GCS	Total: _____ Eye: _____ Verbal: _____ Motoric: _____	<input type="checkbox"/> GCS in intubated patient
mRS	<input type="checkbox"/> <b>0</b> - no symptoms <input type="checkbox"/> <b>1</b> - minor symptoms, no limitations <input type="checkbox"/> <b>2</b> - slight disability, no help needed <input type="checkbox"/> <b>3</b> - moderate disability, needs help but walks without assistance <input type="checkbox"/> <b>4</b> - moderate severe disabled, not able to walk <input type="checkbox"/> <b>5</b> - severe disability, bedridden <input type="checkbox"/> <b>6</b> - dead	

**Baseline laboratory**

Blood samples obtained and sent	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
Source of blood	<input type="checkbox"/> arterial	<input type="checkbox"/> venous	<input type="checkbox"/> unknown
Time to aliquotation	_____ / _____	<input type="checkbox"/> unknown	
Time to freezing	_____ / _____	<input type="checkbox"/> unknown	
NfL	_____		
GFAP	_____		
S100B	_____		
IL-1 $\alpha$	_____	IL-1 $\beta$	_____
IL-2	_____	IL-4	_____
IL-5	_____	IL-6	_____
IL-8	_____	IL-10	_____
IL-12p70	_____	TNF $\alpha$	_____
<b>Coagulation</b>			
INR	_____	<input type="checkbox"/> unknown	

## Baseline NIHSS

### 1A Level of consciousness (LOC)

- 0 - Alert
- 1 - Not alert but arousal by minor stimulation
- 2 - Not alert, requires repeated stimulation
- 3 - Comatose, not responsive

### 1C LOC Commands (open eye + hand grip)

- 0 - Both correct
- 1 - one correct
- 2 - neither correct

### 3 Visual

- 0 - No visual loss
- 1 - Partial hemianopia (extinction)
- 2 - Complete hemianopia
- 3 - Bilateral hemianopia (blindness)

### 5A Motor left arm (45° if supine/90° if sitting extension)

- 0 - no drift, holds for full 10 seconds
- 1 - Drift, drifts down before 10 seconds
- 2 - Effort against gravity
- 3 - No effort against gravity
- 4 - No movement
- UN - untestable: \_\_\_\_\_

### 6A Motor left leg (supine, 30° extension)

- 0 - no drift, holds for full 5 seconds
- 1 - Drift, drifts down before 5 seconds
- 2 - Effort against gravity
- 3 - No effort against gravity
- 4 - No movement
- UN - untestable: \_\_\_\_\_

### 7 Limb ataxia (eyes open/finger-nose/heel-shin)

- 0 - Absent
- 1 - Present in one limb
- 2 - Present in two limbs
- UN - Amputation/joint fusion \_\_\_\_\_

### 9 Best Language

- 0 - No aphasia
- 1 - mild to moderate aphasia
- 2 - severe aphasia (fragmented)
- 3 - mute/global aphasia/coma

**Total:**

### 1B LOC Questions (Age/ current month)

- 0 - Both correct
- 1 - one correct (intubated/language barrier)
- 2 - neither correct (aphasic/stuporous)

### 2 Best gaze (horizontal eye movement)

- 0 - normal
- 1 - partial gaze palsy (one or both eyes)
- 2 - forced deviation/total gaze palsy

### 4 Facial palsy (show teeth and close eyes)

- 0 - Normal
- 1 - minor paralysis (asymmetry on smiling)
- 2 - partial paralysis (near total lower face)
- 3 - Complete paralysis

### 5A Motor right arm (45° if supine/90° if sitting extension)

- 0 - no drift, holds for full 10 seconds
- 1 - Drift, drifts down before 10 seconds
- 2 - Effort against gravity
- 3 - No effort against gravity
- 4 - No movement
- UN - untestable: \_\_\_\_\_

### 6B Motor right leg (supine, 30° extension)

- 0 - no drift, holds for full 5 seconds
- 1 - Drift, drifts down before 5 seconds
- 2 - Effort against gravity
- 3 - No effort against gravity
- 4 - No movement
- UN - untestable: \_\_\_\_\_

### 8 Sensory

- 0 - normal
- 1 - mild to moderate sensory loss
- 2 - sever to total sensory loss

### 10 Dysarthria

- 0 - Normal
- 1 - mild to moderate (slurring)
- 2 - severe dysarthria (unintelligible)
- UN - Intubated/physical barrier \_\_\_\_\_

### 11 Extinction (Neglect)

- 0 - normal
- 1 - visual/tactile/spatial/personal/auditory inattention
- 2 - profound hemi-inattention

### Acute treatment at baseline

Invasive treatment of hypertension	<input type="checkbox"/> yes	<input type="checkbox"/> no	
Anticoagulant reversal	<input type="checkbox"/> yes	<input type="checkbox"/> no	(e.g. Tranexamic acid etc.)
Seizure management	<input type="checkbox"/> yes	<input type="checkbox"/> no	
Blood glucose control	<input type="checkbox"/> yes	<input type="checkbox"/> no	
Withhold treatment due to DNR	<input type="checkbox"/> yes	<input type="checkbox"/> no	
No ICU treatment	<input type="checkbox"/> yes	<input type="checkbox"/> no	

### Baseline SAE

SAE observed	<input type="checkbox"/> yes	<input type="checkbox"/> no
If yes, specify (multiple answers possible)	<input type="checkbox"/> ischemic stroke <input type="checkbox"/> recurrent ICH <input type="checkbox"/> surgical site infection <input type="checkbox"/> any other infection (i.e. pneumonia) <input type="checkbox"/> epileptic seizure <input type="checkbox"/> any need for open neurosurgery <input type="checkbox"/> any other complication prolonging hospital stay/leading to additional treatment <input type="checkbox"/> mortality <input type="checkbox"/> other: _____	
SAE form filled out	<input type="checkbox"/> yes	<input type="checkbox"/> no

### Comments

### Signature and Date

Signature Examiner	Stamp
Date Examination	

## **V2: Day 1 assessment: 24 ± 6 hours after start of treatment**

### **Surgical Baseline data**

Date surgery	____/____/____	Time arrival in OR (Einfahrt Saal)	____:____
Time first cut	____:____		
Duration to intervention (onset-surgical measures)	____ hour(s): ____ min		
Surgery performed in hybrid OR	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
Device for ICH removal	<input type="checkbox"/> Artemis (Penumbra) <input type="checkbox"/> Normal Suction device <input type="checkbox"/> other: _____		<input type="checkbox"/> unknown
Transparent sheath used	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
Neuronavigation	<input type="checkbox"/> BrainLab <input type="checkbox"/> Medtronic <input type="checkbox"/> other : _____		<input type="checkbox"/> unknown
Endoscope	<input type="checkbox"/> Storz <input type="checkbox"/> Stryker <input type="checkbox"/> Minop <input type="checkbox"/> Olympus <input type="checkbox"/> other : _____		<input type="checkbox"/> unknown
Conversion to CC	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
Intraoperative complications	<input type="checkbox"/> no <input type="checkbox"/> seizure <input type="checkbox"/> active bleeding <input type="checkbox"/> other : _____		<input type="checkbox"/> unknown
Intraoperative CT performed (Hybrid OR only)	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
Post-operative CT performed	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
Satisfactory hematoma evacuation (<15mL residual hematoma)	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
ICH volume BrainLab (cm <sup>3</sup> )	_____		
Change of volume in mL	_____		
Change of volume in percent	_____		
Restart surgery after residual hematoma on intra or postoperative CT	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
Duration of surgery (Schnitt to Naht)	____ hour(s): ____ min		

### Day 1 clinical examination

Blood pressure  
(SBP/DBP; mmHg) \_\_\_\_\_ / \_\_\_\_\_

Heart rate (bpm) \_\_\_\_\_

Body temperature  
(°C) \_\_\_\_\_

GCS

Total: \_\_\_\_\_

Eye: \_\_\_\_\_

Verbal: \_\_\_\_\_

Motoric: \_\_\_\_\_

GCS in intubated  
patient

mRS

**0** - no symptoms

**1** - minor symptoms, no limitations

**2** - slight disability, no help needed

**3** - moderate disability, needs help  
but walks without assistance

**4** - moderate severe disabled, not able  
to walk

**5** - severe disability, bedridden

**6** - dead

### Day 1 radiology (cCT)

ICH volumetry (cm<sup>3</sup>) \_\_\_\_\_

Change of volume in mL \_\_\_\_\_

Change of volume in percent \_\_\_\_\_

Recurrent haemorrhage

yes

no

### Acute treatment at day 1

Invasive treatment of  
hypertension

yes

no

Anticoagulant reversal

yes

no

(e.g. Tranexamic  
acid etc.)

Seizure management

yes

no

Blood glucose control

yes

no

Withhold further  
treatment due to DNR

yes

no

No ICU treatment

yes

no



**Day 1 NIHSS**
**1A Level of consciousness (LOC)**

- 0** - Alert  
 **1** - Not alert but arousal by minor stimulation  
 **2** - Not alert, requires repeated stimulation  
 **3** - Comatose, not responsive

**1C LOC Commands (open eye + hand grip)**

- 0** - Both correct  
 **1** - one correct  
 **2** - neither correct

**3 Visual**

- 0** - No visual loss  
 **1** - Partial hemianopia (extinction)  
 **2** - Complete hemianopia  
 **3** - Bilateral hemianopia (blindness)

**5A Motor left arm (45° if supine/90° if sitting extension)**

- 0** - no drift, holds for full 10 seconds  
 **1** - Drift, drifts down before 10 seconds  
 **2** - Effort against gravity  
 **3** - No effort against gravity  
 **4** - No movement  
 **UN** - untestable: \_\_\_\_\_

**6A Motor left leg (supine, 30° extension)**

- 0** - no drift, holds for full 5 seconds  
 **1** - Drift, drifts down before 5 seconds  
 **2** - Effort against gravity  
 **3** - No effort against gravity  
 **4** - No movement  
 **UN** - untestable: \_\_\_\_\_

**7 Limb ataxia (eyes open/finger-nose/heel-shin)**

- 0** - Absent  
 **1** - Present in one limb  
 **2** - Present in two limbs  
 **UN** - Amputation/joint fusion \_\_\_\_\_

**9 Best Language**

- 0** - No aphasia  
 **1** - mild to moderate aphasia  
 **2** - severe aphasia (fragmented)  
 **3** - mute/global aphasia/coma

**Total:**
**1B LOC Questions (Age/ current month)**

- 0** - Both correct  
 **1** - one correct (intubated/language barrier)  
 **2** - neither correct (aphasic/stuporous)

**2 Best gaze (horizontal eye movement)**

- 0** - normal  
 **1** - partial gaze palsy (one or both eyes)  
 **2** - forced deviation/total gaze palsy

**4 Facial palsy (show teeth and close eyes)**

- 0** - Normal  
 **1** - minor paralysis (asymmetry on smiling)  
 **2** - partial paralysis (near total lower face)  
 **3** - Complete paralysis

**5A Motor right arm (45° if supine/90° if sitting extension)**

- 0** - no drift, holds for full 10 seconds  
 **1** - Drift, drifts down before 10 seconds  
 **2** - Effort against gravity  
 **3** - No effort against gravity  
 **4** - No movement  
 **UN** - untestable: \_\_\_\_\_

**6B Motor right leg (supine, 30° extension)**

- 0** - no drift, holds for full 5 seconds  
 **1** - Drift, drifts down before 5 seconds  
 **2** - Effort against gravity  
 **3** - No effort against gravity  
 **4** - No movement  
 **UN** - untestable: \_\_\_\_\_

**8 Sensory**

- 0** - normal  
 **1** - mild to moderate sensory loss  
 **2** - sever to total sensory loss

**10 Dysarthria**

- 0** - Normal  
 **1** - mild to moderate (slurring)  
 **2** - severe dysarthria (unintelligible)  
 **UN** - Intubated/physical barrier \_\_\_\_\_

**11 Extinction (Neglect)**

- 0** - normal  
 **1** - visual/tactile/spatial/personal/auditory inattention  
 **2** - profound hemi-inattention

### Day 1 Re-surgery (0-24h postOP)

Re-surgery necessary	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
If yes, specify why (multiple answers possible)	<input type="checkbox"/> rebleeding <input type="checkbox"/> intracranial infection <input type="checkbox"/> ICP monitoring <input type="checkbox"/> uncontrollable ICP <input type="checkbox"/> hydrocephalus <input type="checkbox"/> subdural hematoma <input type="checkbox"/> unknown		
Performed surgery (multiple answers possible)	<input type="checkbox"/> ICP monitoring <input type="checkbox"/> decompressive hemi-Craniectomy <input type="checkbox"/> Craniotomy <input type="checkbox"/> ETV <input type="checkbox"/> EVD <input type="checkbox"/> VP-Shunt <input type="checkbox"/> Burr hole <input type="checkbox"/> unknown		
SAE form filled out	<input type="checkbox"/> yes	<input type="checkbox"/> no	

### Day 1 SAE

SAE observed	<input type="checkbox"/> yes	<input type="checkbox"/> no
If yes, specify (multiple answers possible)	<input type="checkbox"/> ischemic stroke <input type="checkbox"/> recurrent ICH <input type="checkbox"/> surgical site infection <input type="checkbox"/> any other infection (i.e. pneumonia) <input type="checkbox"/> epileptic seizure <input type="checkbox"/> any need for open neurosurgery <input type="checkbox"/> any other complication prolonging hospital stay/leading to additional treatment <input type="checkbox"/> mortality <input type="checkbox"/> other: _____	
SAE form filled out	<input type="checkbox"/> yes	<input type="checkbox"/> no

### Comments

### Signature and Date

Signature Examiner	Stamp
Date Examination	

## **V3: Day 3 assessment: 72 ± 12 hours after start of treatment**

### **Day 3 clinical examination**

Blood pressure (SBP/DBP; mmHg)	_____ / _____	
Heart rate (bpm)	_____	
Body temperature (°C)	_____	
GCS	Total: _____ Eye: _____ Verbal: _____ Motoric: _____	<input type="checkbox"/> GCS in intubated patient
mRS	<input type="checkbox"/> 0 - no symptoms <input type="checkbox"/> 1 - minor symptoms, no limitations <input type="checkbox"/> 2 – slight disability, no help needed <input type="checkbox"/> 3 – moderate disability, needs help but walks without assistance <input type="checkbox"/> 4 – moderate severe disabled, not able to walk <input type="checkbox"/> 5 - severe disability, bedridden <input type="checkbox"/> 6 - dead	

### **Day 3 laboratory**

Blood samples obtained and sent	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
Source of blood	<input type="checkbox"/> arterial	<input type="checkbox"/> venous	<input type="checkbox"/> unknown
Time to aliquotation	_____ / _____	<input type="checkbox"/> unknown	
Time to freezing	_____ / _____	<input type="checkbox"/> unknown	
NfL	_____		
GFAP	_____		
S100B	_____		
IL-1α	_____	IL-1β	_____
IL-2	_____	IL-4	_____
IL-5	_____	IL-6	_____
IL-8	_____	IL-10	_____
IL-12p70	_____	TNFα	_____

### **Acute treatment at day 3**

Invasive treatment of hypertension	<input type="checkbox"/> yes	<input type="checkbox"/> no	
Anticoagulant reversal	<input type="checkbox"/> yes	<input type="checkbox"/> no	(e.g. Tranexamic acid etc.)
Seizure management	<input type="checkbox"/> yes	<input type="checkbox"/> no	
Blood glucose control	<input type="checkbox"/> yes	<input type="checkbox"/> no	
Withhold further treatment due to DNR	<input type="checkbox"/> yes	<input type="checkbox"/> no	
No ICU treatment	<input type="checkbox"/> yes	<input type="checkbox"/> no	

### Day 3 NIHSS

#### 1A Level of consciousness (LOC)

- 0 - Alert
- 1 – Not alert but arousal by minor stimulation
- 2 – Not alert, requires repeated stimulation
- 3 – Comatose, not responsive

#### 1C LOC Commands (open eye + hand grip)

- 0 – Both correct
- 1 – one correct
- 2 – neither correct

#### 3 Visual

- 0 – No visual loss
- 1 – Partial hemianopia (extinction)
- 2 – Complete hemianopia
- 3 – Bilateral hemianopia (blindness)

#### 5A Motor left arm (45° if supine/90° if sitting extension)

- 0 – no drift, holds for full 10 seconds
- 1 – Drift, drifts down before 10 seconds
- 2 – Effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- UN – untestable: \_\_\_\_\_

#### 6A Motor left leg (supine, 30° extension)

- 0 – no drift, holds for full 5 seconds
- 1 – Drift, drifts down before 5 seconds
- 2 – Effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- UN – untestable: \_\_\_\_\_

#### 7 Limb ataxia (eyes open/finger-nose/heel-shin)

- 0 – Absent
- 1 – Present in one limb
- 2 – Present in two limbs
- UN – Amputation/joint fusion \_\_\_\_\_

#### 9 Best Language

- 0 – No aphasia
- 1 – mild to moderate aphasia
- 2 – severe aphasia (fragmented)
- 3 – mute/global aphasia/coma

#### 1B LOC Questions (Age/ current month)

- 0 – Both correct
- 1 – one correct (intubated/language barrier)
- 2 – neither correct (aphasic/stuporous)

#### 2 Best gaze (horizontal eye movement)

- 0 – normal
- 1 – partial gaze palsy (one or both eyes)
- 2 – forced deviation/total gaze palsy

#### 4 Facial palsy (show teeth and close eyes)

- 0 - Normal
- 1 – minor paralysis (asymmetry on smiling)
- 2 – partial paralysis (near total lower face)
- 3 – Complete paralysis

#### 5A Motor right arm (45° if supine/90° if sitting extension)

- 0 – no drift, holds for full 10 seconds
- 1 – Drift, drifts down before 10 seconds
- 2 – Effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- UN – untestable: \_\_\_\_\_

#### 6B Motor right leg (supine, 30° extension)

- 0 – no drift, holds for full 5 seconds
- 1 – Drift, drifts down before 5 seconds
- 2 – Effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- UN – untestable: \_\_\_\_\_

#### 8 Sensory

- 0 – normal
- 1 – mild to moderate sensory loss
- 2 – sever to total sensory loss

#### 10 Dysarthria

- 0 - Normal
- 1 – mild to moderate (slurring)
- 2 – severe dysarthria (unintelligible)
- UN – Intubated/physical barrier \_\_\_\_\_

#### 11 Extinction (Neglect)

- 0 – normal
- 1 – visual/tactile/spatial/personal/auditory inattention
- 2 – profound hemi-inattention

**Total:**

**Day 3 Re-surgery (0-72h postOP)**

Re-surgery necessary	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
If yes, specify why (multiple answers possible)	<input type="checkbox"/> rebleeding <input type="checkbox"/> intracranial infection <input type="checkbox"/> ICP monitoring <input type="checkbox"/> uncontrollable ICP <input type="checkbox"/> hydrocephalus <input type="checkbox"/> subdural hematoma <input type="checkbox"/> unknown		
Performed surgery (multiple answers possible)	<input type="checkbox"/> ICP monitoring <input type="checkbox"/> decompressive hemi-Craniectomy <input type="checkbox"/> Craniotomy <input type="checkbox"/> ETV <input type="checkbox"/> EVD <input type="checkbox"/> VP-Shunt <input type="checkbox"/> Burr hole <input type="checkbox"/> unknown		
SAE form filled out	<input type="checkbox"/> yes	<input type="checkbox"/> no	

**Day 3 SAE**

SAE observed	<input type="checkbox"/> yes	<input type="checkbox"/> no
If yes, specify (multiple answers possible)	<input type="checkbox"/> ischemic stroke <input type="checkbox"/> recurrent ICH <input type="checkbox"/> surgical site infection <input type="checkbox"/> any other infection (i.e. pneumonia) <input type="checkbox"/> epileptic seizure <input type="checkbox"/> any need for open neurosurgery <input type="checkbox"/> any other complication prolonging hospital stay/leading to additional treatment <input type="checkbox"/> mortality <input type="checkbox"/> other: _____	
SAE form filled out	<input type="checkbox"/> yes	<input type="checkbox"/> no

**Comments**


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**Signature and Date**

Signature Examiner	Stamp
Date Examination	

## **V4: Day 7 assessment: 7 days after start of treatment / discharge**

### **Day 7 clinical examination**

Blood pressure (SBP/DBP; mmHg) \_\_\_\_\_/\_\_\_\_\_

Heart rate (bpm) \_\_\_\_\_

Body temperature (°C) \_\_\_\_\_

GCS Total: \_\_\_\_\_  GCS in intubated patient  
 Eye: \_\_\_\_\_  
 Verbal: \_\_\_\_\_  
 Motoric: \_\_\_\_\_

mRS  0 - no symptoms  
 1 - minor symptoms, no limitations  
 2 – slight disability, no help needed  
 3 – moderate disability, needs help but walks without assistance  
 4 – moderate sever disabled, not able to walk  
 5 - severe disability, bedridden  
 6 - dead

### **Day 7 Re-surgery**

Re-surgery necessary  yes  no  unknown

If yes, specify why (multiple answers possible)  rebleeding  unknown  
 intracranial infection  
 ICP monitoring  
 uncontrollable ICP  
 hydrocephalus  
 subdural hematoma

Performed surgery (multiple answers possible)  ICP monitoring  unknown  
 decompressive hemi-Craniectomy  
 Craniotomy  
 ETV  
 EVD  
 VP-Shunt  
 Burr hole

SAE form filled out  yes  no

## Day 7 NIHSS

### 1A Level of consciousness (LOC)

- 0 - Alert
- 1 - Not alert but arousal by minor stimulation
- 2 - Not alert, requires repeated stimulation
- 3 - Comatose, not responsive

### 1C LOC Commands (open eye + hand grip)

- 0 - Both correct
- 1 - one correct
- 2 - neither correct

### 3 Visual

- 0 - No visual loss
- 1 - Partial hemianopia (extinction)
- 2 - Complete hemianopia
- 3 - Bilateral hemianopia (blindness)

### 5A Motor left arm (45° if supine/90° if sitting extension)

- 0 - no drift, holds for full 10 seconds
- 1 - Drift, drifts down before 10 seconds
- 2 - Effort against gravity
- 3 - No effort against gravity
- 4 - No movement
- UN - untestable: \_\_\_\_\_

### 6A Motor left leg (supine, 30° extension)

- 0 - no drift, holds for full 5 seconds
- 1 - Drift, drifts down before 5 seconds
- 2 - Effort against gravity
- 3 - No effort against gravity
- 4 - No movement
- UN - untestable: \_\_\_\_\_

### 7 Limb ataxia (eyes open/finger-nose/heel-shin)

- 0 - Absent
- 1 - Present in one limb
- 2 - Present in two limbs
- UN - Amputation/joint fusion \_\_\_\_\_

### 9 Best Language

- 0 - No aphasia
- 1 - mild to moderate aphasia
- 2 - severe aphasia (fragmented)
- 3 - mute/global aphasia/coma

**Total:**

### 1B LOC Questions (Age/ current month)

- 0 - Both correct
- 1 - one correct (intubated/language barrier)
- 2 - neither correct (aphasic/stuporous)

### 2 Best gaze (horizontal eye movement)

- 0 - normal
- 1 - partial gaze palsy (one or both eyes)
- 2 - forced deviation/total gaze palsy

### 4 Facial palsy (show teeth and close eyes)

- 0 - Normal
- 1 - minor paralysis (asymmetry on smiling)
- 2 - partial paralysis (near total lower face)
- 3 - Complete paralysis

### 5A Motor right arm (45° if supine/90° if sitting extension)

- 0 - no drift, holds for full 10 seconds
- 1 - Drift, drifts down before 10 seconds
- 2 - Effort against gravity
- 3 - No effort against gravity
- 4 - No movement
- UN - untestable: \_\_\_\_\_

### 6B Motor right leg (supine, 30° extension)

- 0 - no drift, holds for full 5 seconds
- 1 - Drift, drifts down before 5 seconds
- 2 - Effort against gravity
- 3 - No effort against gravity
- 4 - No movement
- UN - untestable: \_\_\_\_\_

### 8 Sensory

- 0 - normal
- 1 - mild to moderate sensory loss
- 2 - sever to total sensory loss

### 10 Dysarthria

- 0 - Normal
- 1 - mild to moderate (slurring)
- 2 - severe dysarthria (unintelligible)
- UN - Intubated/physical barrier \_\_\_\_\_

### 11 Extinction (Neglect)

- 0 - normal
- 1 - visual/tactile/spatial/personal/auditory inattention
- 2 - profound hemi-inattention

### Acute treatment at day 7

Invasive treatment of hypertension	<input type="checkbox"/> yes	<input type="checkbox"/> no	
Anticoagulant reversal	<input type="checkbox"/> yes	<input type="checkbox"/> no	(e.g. Tranexamic acid etc.)
Seizure management	<input type="checkbox"/> yes	<input type="checkbox"/> no	
Blood glucose control	<input type="checkbox"/> yes	<input type="checkbox"/> no	
Withhold further treatment due to DNR	<input type="checkbox"/> yes	<input type="checkbox"/> no	
No ICU treatment	<input type="checkbox"/> yes	<input type="checkbox"/> no	

### Day 7 Discharge

Time spent in ICU	____:____ (hh:mm)
Time spent in intubation	____:____ (hh:mm)
Discharge destination	<input type="checkbox"/> rehabilitation centre <input type="checkbox"/> other hospital <input type="checkbox"/> home <input type="checkbox"/> nursing home <input type="checkbox"/> other: _____

### Day 7 SAE

SAE observed	<input type="checkbox"/> yes	<input type="checkbox"/> no
If yes, specify (multiple answers possible)	<input type="checkbox"/> ischemic stroke <input type="checkbox"/> recurrent ICH <input type="checkbox"/> surgical site infection <input type="checkbox"/> any other infection (i.e. pneumonia) <input type="checkbox"/> epileptic seizure <input type="checkbox"/> any need for open neurosurgery <input type="checkbox"/> any other complication prolonging hospital stay/leading to additional treatment <input type="checkbox"/> mortality <input type="checkbox"/> other: _____	
SAE form filled out	<input type="checkbox"/> yes	<input type="checkbox"/> no



**Comments**

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**Signature and Date**

Signature Examiner	_____	Stamp	_____
Date Examination	_____		

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**V5: 3-month assessment: 3 months ± 14 days after start of treatment / discharge**

**3 month clinical examination**

Blood pressure (SBP/DBP; mmHg)	_____ / _____	
Body temperature (°C)	_____	
GCS	Total: _____ Eye: _____ Verbal: _____ Motoric: _____	<input type="checkbox"/> GCS in intubated patient
mRS	<input type="checkbox"/> <b>0</b> - no symptoms <input type="checkbox"/> <b>1</b> - minor symptoms, no limitations <input type="checkbox"/> <b>2</b> – slight disability, no help needed <input type="checkbox"/> <b>3</b> – moderate disability, needs help but walks without assistance <input type="checkbox"/> <b>4</b> – moderate sever disabled, not able to walk <input type="checkbox"/> <b>5</b> - severe disability, bedridden <input type="checkbox"/> <b>6</b> - dead	

**3-month Quality of Life (PROMIS 10)**

1. In general, would you say your health is	_____	Points
2. In general, would you say your quality of life is	_____	Points
3. In general, how would you rate your physical health	_____	Points
4. In general, how would you rate your mental health, including your mood and your ability to think	_____	Points
5. In general, how would you rate your satisfaction with your social activities and relationships	_____	Points
9r. In general, please rate how well you carry out your usual social activities and roles	_____	Points
6. To what extend are you able to carry out your everyday physical activities such as walking, climbing stairs etc	_____	Points
10r. How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable	_____	Points
8r How would you rate your fatigue on average	_____	Points
7rc How would you rate your pain on average	_____	Points

### 3 month NIHSS

#### 1A Level of consciousness (LOC)

- 0 - Alert
- 1 – Not alert but arousal by minor stimulation
- 2 – Not alert, requires repeated stimulation
- 3 – Comatose, not responsive

#### 1C LOC Commands (open eye + hand grip)

- 0 – Both correct
- 1 – one correct
- 2 – neither correct

#### 3 Visual

- 0 – No visual loss
- 1 – Partial hemianopia (extinction)
- 2 – Complete hemianopia
- 3 – Bilateral hemianopia (blindness)

#### 5A Motor left arm (45° if supine/90° if sitting extension)

- 0 – no drift, holds for full 10 seconds
- 1 – Drift, drifts down before 10 seconds
- 2 – Effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- UN – untestable: \_\_\_\_\_

#### 6A Motor left leg (supine, 30° extension)

- 0 – no drift, holds for full 5 seconds
- 1 – Drift, drifts down before 5 seconds
- 2 – Effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- UN – untestable: \_\_\_\_\_

#### 7 Limb ataxia (eyes open/finger-nose/heel-shin)

- 0 – Absent
- 1 – Present in one limb
- 2 – Present in two limbs
- UN – Amputation/joint fusion \_\_\_\_\_

#### 9 Best Language

- 0 – No aphasia
- 1 – mild to moderate aphasia
- 2 – severe aphasia (fragmented)
- 3 – mute/global aphasia/coma

**Total:**

#### 1B LOC Questions (Age/ current month)

- 0 – Both correct
- 1 – one correct (intubated/language barrier)
- 2 – neither correct (aphasic/stuporous)

#### 2 Best gaze (horizontal eye movement)

- 0 – normal
- 1 – partial gaze palsy (one or both eyes)
- 2 – forced deviation/total gaze palsy

#### 4 Facial palsy (show teeth and close eyes)

- 0 - Normal
- 1 – minor paralysis (asymmetry on smiling)
- 2 – partial paralysis (near total lower face)
- 3 – Complete paralysis

#### 5A Motor right arm (45° if supine/90° if sitting extension)

- 0 – no drift, holds for full 10 seconds
- 1 – Drift, drifts down before 10 seconds
- 2 – Effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- UN – untestable: \_\_\_\_\_

#### 6B Motor right leg (supine, 30° extension)

- 0 – no drift, holds for full 5 seconds
- 1 – Drift, drifts down before 5 seconds
- 2 – Effort against gravity
- 3 – No effort against gravity
- 4 – No movement
- UN – untestable: \_\_\_\_\_

#### 8 Sensory

- 0 – normal
- 1 – mild to moderate sensory loss
- 2 – sever to total sensory loss

#### 10 Dysarthria

- 0 - Normal
- 1 – mild to moderate (slurring)
- 2 – severe dysarthria (unintelligible)
- UN – Intubated/physical barrier \_\_\_\_\_

#### 11 Extinction (Neglect)

- 0 – normal
- 1 – visual/tactile/spatial/personal/auditory inattention
- 2 – profound hemi-inattention

### 3 month Re-surgery

Re-surgery necessary	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
If yes, specify why (multiple answers possible)	<input type="checkbox"/> rebleeding <input type="checkbox"/> intracranial infection <input type="checkbox"/> ICP monitoring <input type="checkbox"/> uncontrollable ICP <input type="checkbox"/> hydrocephalus <input type="checkbox"/> subdural hematoma <input type="checkbox"/> unknown		
Performed surgery (multiple answers possible)	<input type="checkbox"/> ICP monitoring <input type="checkbox"/> decompressive hemi-Craniectomy <input type="checkbox"/> Craniotomy <input type="checkbox"/> ETV <input type="checkbox"/> EVD <input type="checkbox"/> VP-Shunt <input type="checkbox"/> Burr hole <input type="checkbox"/> unknown		
SAE form filled out	<input type="checkbox"/> yes	<input type="checkbox"/> no	

### 3-month MOCA

Visuospatial/Executive	_____	Points
Naming	_____	Points
Memory	No Points	
Attention - Number list	_____	Points
Attention – Letter list	_____	Points
Attention - Subtraction	_____	Points
Speech – Repetition	_____	Points
Speech – Word naming	_____	Points
Abstraction	_____	Points
Recollection	_____	Points
Orientation	_____	Points
Total Points	_____	Points (+1 Point if ≤ 12 years of Education)

### 3-month Patient Satisfaction (1-lowest, 5-best)

1. Fühlten Sie sich gut betreut?	_____	Points
2. Wurden alle Ihre Fragen zu Ihrer Zufriedenheit erfüllt (zum Beispiel was passiert in Zukunft?) und fühlten Sie sich ernst genommen?	_____	Points
3. Hatten Sie das Gefühl, dass man sich genug Zeit für Sie genommen hat ( konnten zum Beispiel Ärzte und Pflege genügend auf Ihre Bedürfnisse eingehen)?	_____	Points
4. Wie zufrieden sind Sie mit dem Ergebnis Ihrer Behandlung (Zum Beispiel mit der Entwicklung von körperlichen Einschränkungen)?	_____	Points
5. Wie zufrieden sind Sie gesamthaft mit Ihrer Behandlung (Zum Beispiel mit der Funktion im Alltag)?	_____	Points
Total points	_____	Points

### 3 month SAE

SAE observed	<input type="checkbox"/> yes	<input type="checkbox"/> no
If yes, specify (multiple answers possible)	<input type="checkbox"/> ischemic stroke <input type="checkbox"/> recurrent ICH <input type="checkbox"/> surgical site infection <input type="checkbox"/> any other infection (i.e. pneumonia) <input type="checkbox"/> epileptic seizure <input type="checkbox"/> any need for open neurosurgery <input type="checkbox"/> any other complication prolonging hospital stay/leading to additional treatment <input type="checkbox"/> mortality <input type="checkbox"/> other: _____	
SAE form filled out	<input type="checkbox"/> yes	<input type="checkbox"/> no

### Comments

Pregnancy  
reported?

### Signature and Date

Signature Examiner	Stamp
_____	_____
Date Examination	_____

**V6: 6-month assessment: 6 months ± 28 days after start of treatment / discharge**

**6 month clinical examination**

Blood pressure (SBP/DBP; mmHg) \_\_\_\_\_/\_\_\_\_\_  
Heart rate (bpm) \_\_\_\_\_

Body temperature (°C) \_\_\_\_\_

GCS Total: \_\_\_\_\_  GCS in intubated patient  
Eye: \_\_\_\_\_  
Verbal: \_\_\_\_\_  
Motoric: \_\_\_\_\_

mRS  0 - no symptoms  
 1 - minor symptoms, no limitations  
 2 – slight disability, no help needed  
 3 – moderate disability, needs help but walks without assistance  
 4 – moderate sever disabled, not able to walk  
 5 - severe disability, bedridden  
 6 - dead

**6-month radiology (cCT)**

ICH volumetry (cm<sup>3</sup>) \_\_\_\_\_  
Change of volume in mL \_\_\_\_\_  
Change of volume in percent \_\_\_\_\_  
Residual hematoma  yes  no  
Recurrent haemorrhage  yes  no

**6 month laboratory**

Blood samples obtained and sent  yes  no  unknown  
Source of blood  arterial  venous  unknown  
Time to aliquotation \_\_\_\_\_/\_\_\_\_\_  
Time to freezing \_\_\_\_\_/\_\_\_\_\_  
NfL \_\_\_\_\_  
GFAP \_\_\_\_\_  
S100B \_\_\_\_\_  
IL-1α \_\_\_\_\_ IL-1β \_\_\_\_\_  
IL-2 \_\_\_\_\_ IL-4 \_\_\_\_\_  
IL-5 \_\_\_\_\_ IL-6 \_\_\_\_\_  
IL-8 \_\_\_\_\_ IL-10 \_\_\_\_\_  
IL-12p70 \_\_\_\_\_ TNFα \_\_\_\_\_

### 6 month Re-surgery

Re-surgery necessary	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> unknown
If yes, specify why (multiple answers possible)	<input type="checkbox"/> rebleeding		<input type="checkbox"/> unknown
	<input type="checkbox"/> intracranial infection		
	<input type="checkbox"/> ICP monitoring		
	<input type="checkbox"/> uncontrollable ICP		
	<input type="checkbox"/> hydrocephalus		
Performed surgery (multiple answers possible)	<input type="checkbox"/> subdural hematoma		
	<input type="checkbox"/> ICP monitoring		<input type="checkbox"/> unknown
	<input type="checkbox"/> decompressive hemi-Craniectomy		
	<input type="checkbox"/> Craniotomy		
	<input type="checkbox"/> ETV		
	<input type="checkbox"/> EVD		
	<input type="checkbox"/> VP-Shunt		
<input type="checkbox"/> Burr hole			
SAE form filled out	<input type="checkbox"/> yes	<input type="checkbox"/> no	

### 3-month Quality of Life (PROMIS 10)

1. In general, would you say your health is	_____	Points
2. In general, would you say your quality of life is	_____	Points
3. In general, how would you rate your physical health	_____	Points
4. In general, how would you rate your mental health, including your mood and your ability to think	_____	Points
5. In general, how would you rate your satisfaction with your social activities and relationships	_____	Points
9r. In general, please rate how well you carry out your usual social activities and roles	_____	Points
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10r. How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable	_____	Points
8r How would you rate your fatigue on average	_____	Points
7rc How would you rate your pain on average	_____	Points

## 6 month NIHSS

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- 2 - Effort against gravity
- 3 - No effort against gravity
- 4 - No movement
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### 6A Motor left leg (supine, 30° extension)

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- 1 - Drift, drifts down before 5 seconds
- 2 - Effort against gravity
- 3 - No effort against gravity
- 4 - No movement
- UN - untestable: \_\_\_\_\_

### 7 Limb ataxia (eyes open/finger-nose/heel-shin)

- 0 - Absent
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- 2 - Present in two limbs
- UN - Amputation/joint fusion \_\_\_\_\_

### 9 Best Language

- 0 - No aphasia
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**Total:**

### 1B LOC Questions (Age/ current month)

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- 3 - No effort against gravity
- 4 - No movement
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### 8 Sensory

- 0 - normal
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### 11 Extinction (Neglect)

- 0 - normal
- 1 - visual/tactile/spatial/personal/auditory inattention
- 2 - profound hemi-inattention



**6-month MOCA**

Visuospatial/Executive	_____	Points
Naming	_____	Points
Memory	No Points	
Attention - Number list	_____	Points
Attention – Letter list	_____	Points
Attention - Subtraction	_____	Points
Speech – Repetition	_____	Points
Speech – Word naming	_____	Points
Abstraction	_____	Points
Recollection	_____	Points
Orientation	_____	Points
Total Points	_____	Points (+1 Point if ≤ 12 years of Education)

**6-month Patient Satisfaction (1-lowest, 5-best)**

1. Fühlten Sie sich gut betreut?	_____	Points
2. Wurden alle Ihre Fragen zu Ihrer Zufriedenheit erfüllt (zum Beispiel was passiert in Zukunft?) und fühlten Sie sich ernst genommen?	_____	Points
3. Hatten Sie das Gefühl, dass man sich genug Zeit für Sie genommen hat ( konnten zum Beispiel Ärzte und Pflege genügend auf Ihre Bedürfnisse eingehen)?	_____	Points
4. Wie zufrieden sind Sie mit der Aufklärung für die Zeit nach der Studie (Wurden zum Beispiel Fragen über den zukünftigen Krankheitsverlauf beantwortet)?	_____	Points
5. Wie zufrieden sind Sie gesamthaft mit Ihrer Behandlung (Zum Beispiel mit der Funktion im Alltag)?	_____	Points
Total points	_____	Points

**6 month SAE**

SAE observed	<input type="checkbox"/> yes	<input type="checkbox"/> no
If yes, specify (multiple answers possible)	<input type="checkbox"/> ischemic stroke <input type="checkbox"/> recurrent ICH <input type="checkbox"/> surgical site infection <input type="checkbox"/> any other infection (i.e. pneumonia) <input type="checkbox"/> epileptic seizure <input type="checkbox"/> any need for open neurosurgery <input type="checkbox"/> any other complication prolonging hospital stay/leading to additional treatment <input type="checkbox"/> mortality <input type="checkbox"/> other: _____	
SAE form filled out	<input type="checkbox"/> yes	<input type="checkbox"/> no

**Comments**

Pregnancy reported? \_\_\_\_\_

**Signature and Date**

Signature Examiner \_\_\_\_\_

Stamp \_\_\_\_\_

Date Examination \_\_\_\_\_