

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

Patient sticker/label;

OR:

Patient name: _____ +

Patient ID: _____

DUTCH ICH Surgery trial (pilot) Clinical follow up CRF

Vital parameters at 1, 6 and 12 hours

Name examiner: _____
Date of examination: ___/___/___

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

Name examiner: _____
Date of examination: ___/___/___

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

Name examiner: _____
Date of examination: ___/___/___

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

(S)AE Check at baseline

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

Date of inclusion: ____/____/____

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Patient ID: _____

24 hour follow-up

Physical examination at 24 hours

Name examiner: _____
Date of examination: ____/____/____

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

NIHSS at 24 hours

Name examiner: _____
Date of examination: ____/____/____

<p>1A Level of consciousness (LOC)</p> <p><input type="checkbox"/> 0 – Alert</p> <p><input type="checkbox"/> 1 – Not alert, but arousable</p> <p><input type="checkbox"/> 2 – Not alert, requires repeated stimulation</p> <p><input type="checkbox"/> 3 – Comatose</p> <p>1C LOC Commands</p> <p><input type="checkbox"/> 0 – Performs both tasks correctly</p> <p><input type="checkbox"/> 1 – Performs one task correctly</p> <p><input type="checkbox"/> 2 – Performs neither tasks correctly</p> <p>3 Visual</p> <p><input type="checkbox"/> 0 – No visual loss</p> <p><input type="checkbox"/> 1 – Partial hemianopia</p> <p><input type="checkbox"/> 2 – Complete hemianopia</p> <p><input type="checkbox"/> 3 – Bilateral hemianopia</p> <p>5A Motor left arm</p> <p><input type="checkbox"/> 0 – No drift</p> <p><input type="checkbox"/> 1 – Drift</p> <p><input type="checkbox"/> 2 – Some effort against gravity</p> <p><input type="checkbox"/> 3 – No effort against gravity</p> <p><input type="checkbox"/> 4 – No movement</p> <p><input type="checkbox"/> 0 – Untestable, explain reason: _____</p> <p>6A Motor left leg</p> <p><input type="checkbox"/> 0 – No drift</p> <p><input type="checkbox"/> 1 – Drift</p> <p><input type="checkbox"/> 2 – Some effort against gravity</p> <p><input type="checkbox"/> 3 – No effort against gravity</p> <p><input type="checkbox"/> 4 – No movement</p> <p><input type="checkbox"/> 0 – Untestable, explain reason: _____</p> <p>7 Limb ataxia</p> <p><input type="checkbox"/> 0 – Absent</p> <p><input type="checkbox"/> 1 – Present in one limb</p> <p><input type="checkbox"/> 2 – Present in two limbs</p> <p>9 Best language</p> <p><input type="checkbox"/> 0 – No aphasia (normal)</p> <p><input type="checkbox"/> 1 – Mild to moderate aphasia</p> <p><input type="checkbox"/> 2 – Severe aphasia</p> <p><input type="checkbox"/> 3 – Mute, global aphasia</p> <p>11 Extinction and inattention</p> <p><input type="checkbox"/> 0 – No abnormality</p> <p><input type="checkbox"/> 1 – Inattention 1 modality /extinction</p> <p><input type="checkbox"/> 2 – Profound hemi-inattention or extinction</p>	<p>1B LOC Questions</p> <p><input type="checkbox"/> 0 – Answers both questions correctly</p> <p><input type="checkbox"/> 1 – Answers one question correctly</p> <p><input type="checkbox"/> 2 – Answers neither questions correctly</p> <p>2 Best gaze</p> <p><input type="checkbox"/> 0 – Normal</p> <p><input type="checkbox"/> 1 – Partial gaze palsy</p> <p><input type="checkbox"/> 2 – Forced deviation</p> <p>4 Facial palsy</p> <p><input type="checkbox"/> 0 – Normal</p> <p><input type="checkbox"/> 1 – Minor paralysis</p> <p><input type="checkbox"/> 2 – Partial paralysis</p> <p><input type="checkbox"/> 3 – Complete paralysis</p> <p>5B Motor right arm</p> <p><input type="checkbox"/> 0 – No drift</p> <p><input type="checkbox"/> 1 – Drift</p> <p><input type="checkbox"/> 2 – Some effort against gravity</p> <p><input type="checkbox"/> 3 – No effort against gravity</p> <p><input type="checkbox"/> 4 – No movement</p> <p><input type="checkbox"/> 0 – Untestable, explain reason: _____</p> <p>6B Motor right leg</p> <p><input type="checkbox"/> 0 – No drift</p> <p><input type="checkbox"/> 1 – Drift</p> <p><input type="checkbox"/> 2 – Some effort against gravity</p> <p><input type="checkbox"/> 3 – No effort against gravity</p> <p><input type="checkbox"/> 4 – No movement</p> <p><input type="checkbox"/> 0 – Untestable, explain reason: _____</p> <p>8 Sensory</p> <p><input type="checkbox"/> 0 – Normal</p> <p><input type="checkbox"/> 1 – Mild to moderate sensory loss</p> <p><input type="checkbox"/> 2 – Severe or total sensory loss</p> <p>10 Dysarthria</p> <p><input type="checkbox"/> 0 – Normal</p> <p><input type="checkbox"/> 1 – Mild to moderate dysarthria</p> <p><input type="checkbox"/> 2 – Severe dysarthria, anarthria, mute</p> <p><input type="checkbox"/> 0 – Intubated, or other, explain: _____</p> <p style="text-align: center;"><i>(modalities: visual/tactile/auditory/spatial/personal)</i></p>
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(S)AE Check at 24 hours

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



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7-day (or discharge, if earlier) follow-up

Name examiner: _____

Date of examination: ___/___/___

Vital parameters at 7 days or discharge:

Round numbers

Systolic blood pressure _____ mm Hg
Heart rate _____ /min

Diastolic blood pressure _____ mm Hg

Name examiner: _____

Date of examination: ___/___/___

modified Rankin Scale (mRS) score at 7 days or discharge

- 0 No symptoms
- 1 Minor symptoms, no limitations
- 2 Slight disability, no help needed
- 3 Moderate disability, requires some help but able to walk on assistance
- 4 Moderate severe disability
- 5 Severe disability, completely dependent
- 6 Death

Date of death: ___/___/___ (please fill out SAE form)

NIHSS at 7 days or discharge

Name examiner: _____

Date of examination: ___/___/___

1A Level of consciousness (LOC)

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

1B LOC Questions

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

1C LOC Commands

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

2 Best gaze

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

3 Visual

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

4 Facial palsy

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

5A Motor left arm

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

5B Motor right arm

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

6A Motor left leg

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

6B Motor right leg

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

7 Limb ataxia

- 0 – Absent
- 1 – Present in one limb
- 2 – Present in two limbs

8 Sensory

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

9 Best language

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

10 Dysarthria

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



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Patient ID: _____

11 Extinction and inattention

- 0 – No abnormality
- 1 – Inattention 1 modality /extinction
- 2 – Profound hemi-inattention or extinction

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

Discharge

Neuroimaging

Other neuroimaging performed during clinical follow-up? No Yes

- If yes, specify:
- NCCT No Yes
 - CT-a No Yes
 - MRI No Yes
 - MRA No Yes
 - DSA No Yes

Interventions and diagnoses during hospital stay

Neurological deterioration No Yes

Recurrent intracerebral hemorrhage No Yes

(please fill out SAE form)
 If yes, specify: **(please fill out SAE form)**
 Symptomatic No Yes
 Rebleed No Yes

- Diagnoses of (new) cancer No Yes
- Intracranial infection No Yes
- Seizure(s) No Yes
- Intubation (excluding intubation for surgery) No Yes
- Surgical intervention (excluding study surgery) No Yes

(please fill out SAE form)
(please fill out SAE form)
(please fill out SAE form)

- If yes, specify:
- External ventricular drain (EVD) No Yes
 - Hemicraniectomy No Yes
 - Hematoma evacuation No Yes
 - ICP monitoring No Yes
 - Burr hole(s) No Yes

(please fill out SAE form)
 Date of intervention: ___/___/___
 Date of intervention: ___/___/___
 Date of intervention: ___/___/___
 Date of intervention: ___/___/___
 Date of intervention: ___/___/___
 If yes, **fill out SAE form** and describe: _____
 Date of intervention: ___/___/___

Other major medical intervention: _____

Antihypertensive medication during hospital stay

- Any type of antihypertensive medication No Yes:
- ACE inhibitor No Yes
 - Angiotensin II receptor antagonist No Yes
 - Beta blocker No Yes
 - Calcium channel blocker No Yes
 - Diuretic No Yes
 - Intravenous labetalol No Yes
 - Other: _____

If applicable:

Start date	___/___/___	Stop date	___/___/___
Start date	___/___/___	Stop date	___/___/___
Start date	___/___/___	Stop date	___/___/___
Start date	___/___/___	Stop date	___/___/___
Start date	___/___/___	Stop date	___/___/___
Start date	___/___/___	Stop date	___/___/___

Platelet inhibitor(s) during hospital stay

- Any type of platelet inhibitor No Yes
- Acetylsalicylic acid/carbasalate calcium No Yes
 - Clopidogrel No Yes
 - Dipyridamol No Yes
 - Ticagrelor No Yes
 - Other: _____

If applicable:

Start date	___/___/___	Stop date	___/___/___
Start date	___/___/___	Stop date	___/___/___
Start date	___/___/___	Stop date	___/___/___
Start date	___/___/___	Stop date	___/___/___

Direct oral anticoagulant (DOAC) during hospital stay

- Any type of DOAC No Yes
- Apixaban (Eliquis®) No Yes
 - Dabigatran (Pradaxa®) No Yes
 - Edoxaban (Lixiana®) No Yes
 - Rivaroxaban (Xarelto®) No Yes

If applicable:

Start date	___/___/___	Stop date	___/___/___
Start date	___/___/___	Stop date	___/___/___
Start date	___/___/___	Stop date	___/___/___
Start date	___/___/___	Stop date	___/___/___



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Other: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Vitamin K antagonist(s) during stay	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Heparin during hospital stay			<i>If applicable:</i>
Any type of heparin	<input type="checkbox"/> No <input type="checkbox"/> Yes:		
Prophylactic heparin	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Therapeutic heparin	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Admission			
Was the patient admitted to the:		Total number of days in:	
- ICU	<input type="checkbox"/> No <input type="checkbox"/> Yes	- ICU	_____
- Medium care	<input type="checkbox"/> No <input type="checkbox"/> Yes	- Medium care	_____
- Stroke Unit	<input type="checkbox"/> No <input type="checkbox"/> Yes	- Stroke Unit	_____
- General ward (not stroke unit)	<input type="checkbox"/> No <input type="checkbox"/> Yes	- General ward	_____
Discharge (dead or alive)			
Was the patient discharged	<input type="checkbox"/> No <input type="checkbox"/> Yes	<u>Discharge destination:</u>	
Date of discharge (dead or alive)	___/___/___	<input type="checkbox"/> 0 - Patient died (please fill out SAE form)	
		<input type="checkbox"/> 1 - Home	
		<input type="checkbox"/> 2 - Other hospital	
		<input type="checkbox"/> 3 - Geriatric rehabilitation	
		<input type="checkbox"/> 4 - Nursing home long stay	
		<input type="checkbox"/> 5 - Rehabilitation center	
		<input type="checkbox"/> 6 - Other: _____	
		<input type="checkbox"/> 9 - Unkown	

(S)AE Check at discharge

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