



MR CLEAN-MED:

Multicenter Randomized CLinical trial of Endovascular treatment for Acute ischemic stroke in the Netherlands. The effect of periprocedural MEDication: heparin, antiplatelet agents, both or neither.

Case Report Forms (CRFs) ON PAPER

Version 1.0, April 2018

Study number: _____

Inclusion date (DD/MM/YYYY): __ / __ / _____

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

Kind regards,

The MR CLEAN-MED team

Rob A. van de Graaf & Bob Roozenbeek, Coordinating researchers

Diederik W.J. Dippel & Aad van der Lugt, Principle investigators

mrclean.med@erasmusmc.nl

www.mrclean-med.nl

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

BASELINE CRF

Medical history/Comorbidities at baseline

Medical history of:

- Atrial fibrillation No Yes
- Diabetes mellitus No Yes
- Chronic heart failure No Yes
- Hypertension No Yes
- Hypercholesterolemia No Yes
- Intracranial hemorrhage No Yes
- Mechanical aorta and/or mitral valve replacement No Yes
- Myocardial infarction No Yes
- Peripheral artery disease No Yes
- Previous ischemic stroke No Yes
- Smoking (currently or in the past 6 months) No Yes

Medication (home) – use of:

Antiplatelet agent(s) No Yes:

Specify:

- Acetylsalicylic acid/carbasalate calcium No Yes
- Clopidogrel No Yes
- Dipyridamol No Yes
- Ticagrelor No Yes
- Other: _____

- Antihypertensive drug(s) No Yes
- Benzodiazepine No Yes
- Vitamin K antagonist No Yes
- Direct oral anticoagulant (DOAC) No Yes
- Therapeutic heparin (all types, including LMWH) No Yes
- NSAID No Yes
- Statin No Yes

Pre-stroke modified Rankin Scale (mRS) score

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

Pre-mRS 3-5 is an exclusion criterion, re-evaluate

Physical examination at baseline

Glasgow coma Scale

Eye

- 4 - Opens eyes spontaneously
- 3 - Opens eyes in response to voice
- 2 - Opens eyes in resp. to painful stimuli
- 1 - Does not open eyes

Motor

- 6 - Obeys commands
- 5 - Localizes painful stimuli
- 4 - Flexion/withdrawal to painful stimuli
- 3 - Abnormal flexion to painful stimuli
- 2 - Extension to painful stimuli
- 1 - Makes no movements

Verbal

- 5 - Oriented/converses normally
- 4 - Confused/disoriented
- 3 - Utters inappropriate words
- 2 - Incomprehensible sounds
- 1 - Makes no sounds

Vital parameters - first intra-hospital/ER:

Round numbers except for body temp (1 decimal)

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

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

NIHSS at baseline

1A. Level of consciousness (LOC)

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

1B. LOC Questions

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

1C. LOC Commands

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

2. Best gaze

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

3. Visual

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

4. Facial palsy

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

5A. Motor left arm

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

5B. Motor right arm

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

6A. Motor left leg

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

6B. Motor right leg

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

7. Limb ataxia

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

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
- 9 – Intubated or other, explain: _____

11. Extinction and inattention

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

Laboratory results at baseline

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

APTT	_____ sec	CRP	_____ mg/L
INR	____ . ____	Serum creatinine	_____ umol/L
Thrombocyte count	_____ *10 ⁹	Serum glucose	____ . ____ mmol/L

CONTRAST Biobank study blood sample at baseline

Did you take a study blood sample after randomization (± 1 hour before intra-arterial treatment if applicable)? No Yes

Did you take a study blood sample ± 1 hour after randomization or intra-arterial treatment? No Yes

(S)AE Check at baseline

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

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

MR CLEAN-MED STUDY TREATMENT CRF

Acetylsalicylic acid

Acetylsalicylic acid (Aspégic) given

No Yes:

If Yes:

Dose given

300 mg Other: _____ mg,
and explain why other dose was given:

Time of dose given

Charge number

____:____ hh:mm

Heparin

I. Heparin loading dose given

No Yes

If Yes:

Dose given

5000 IU Other _____ IU,
and explain why other loading dose was given:

Time of bolus

Charge number

____:____ hh:mm

II. Heparin continuous infusion started (after loading dose)

No (specify below) Yes

If Yes:

Infusion speed per hour (during 6 hours)

Infusion speed changed or stopped early

500 IU/h 1250 IU/h Other: _____ IU/h

No Changed Stopped

If Changed, provide speed: _____ IU/h

Deviated from study

Please specify if deviated from study and provide reason:

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

CLINICAL FOLLOW-UP CRF

NIHSS at 24 hours

Date of NIHSS assessment: ___/___/___

1A. Level of consciousness (LOC)

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

1B. LOC Questions

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

1C. LOC Commands

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

2. Best gaze

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

3. Visual

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

4. Facial palsy

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

5A. Motor left arm

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

5B. Motor right arm

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

6A. Motor left leg

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

6B. Motor right leg

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

7. Limb ataxia

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

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
- 9 – Intubated or other, explain: _____

11. Extinction and inattention

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

CONTRAST Biobank study blood sample at 24 hours

Did you take a study blood sample at 24 hours? No Yes

(S)AE Check at 24 hours

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

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

NIHSS at 5-7 days (or discharge, if earlier)

Date of NIHSS assessment: ___/___/___

1A. Level of consciousness (LOC)

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

1B. LOC Questions

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

1C. LOC Commands

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

2. Best gaze

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

3. Visual

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

4. Facial palsy

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

5A. Motor left arm

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

5B. Motor right arm

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

6A. Motor left leg

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

6B. Motor right leg

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

7. Limb ataxia

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

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
- 9 – Intubated or other, explain: _____

11. Extinction and inattention

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

(S)AE Check at 5-7 days

Did the patient experience one or more (serious) adverse event(s)?

No Yes (if Yes, please complete (S)AE form(s))

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

Discharge – Intervention center

Neuroimaging

- CT(A) at 24 hours performed? No Yes
- CT at 5-7 days performed? No Yes
- MRI at 5-7 days performed? No Yes
- Other neuroimaging performed during hospital stay? No Yes

Antithrombotic agents during hospital stay

- Any type of antithrombotic agents started? No Yes:
- If applicable:*
- | | | | | |
|---|--|------------------------|--------------|-----------------------|
| Acetylsalicylic acid/ carbasalate calcium | <input type="checkbox"/> No <input type="checkbox"/> Yes | Start date ___/___/___ | Time ___:___ | Stop date ___/___/___ |
| Clopidogrel | <input type="checkbox"/> No <input type="checkbox"/> Yes | Start date ___/___/___ | Time ___:___ | Stop date ___/___/___ |
| Dipyridamol | <input type="checkbox"/> No <input type="checkbox"/> Yes | Start date ___/___/___ | Time ___:___ | Stop date ___/___/___ |
| Ticagrelor | <input type="checkbox"/> No <input type="checkbox"/> Yes | Start date ___/___/___ | Time ___:___ | Stop date ___/___/___ |
| Prophylactic heparin | <input type="checkbox"/> No <input type="checkbox"/> Yes | Start date ___/___/___ | Time ___:___ | Stop date ___/___/___ |
| Therapeutic heparin | <input type="checkbox"/> No <input type="checkbox"/> Yes | Start date ___/___/___ | Time ___:___ | Stop date ___/___/___ |
| Vitamin K antagonist | <input type="checkbox"/> No <input type="checkbox"/> Yes | Start date ___/___/___ | Time ___:___ | Stop date ___/___/___ |
| Direct oral anticoagulant (DOAC) | <input type="checkbox"/> No <input type="checkbox"/> Yes | Start date ___/___/___ | Time ___:___ | Stop date ___/___/___ |
| Other: _____ | | Start date ___/___/___ | Time ___:___ | Stop date ___/___/___ |
| Other: _____ | | Start date ___/___/___ | Time ___:___ | Stop date ___/___/___ |

Interventions and diagnoses during hospital stay

- | | | | |
|-----------------------------|---|------------|---|
| Atrial fibrillation de novo | <input type="checkbox"/> No <input type="checkbox"/> Yes | Treatment: | <input type="checkbox"/> 0 - No |
| Aneurysma spurium | <input type="checkbox"/> No <input type="checkbox"/> Yes: | | <input type="checkbox"/> 1 - (Pro)thrombin injection |
| | | | <input type="checkbox"/> 2 - Compression bandage |
| | | | <input type="checkbox"/> 3 - Surgical intervention (fill out SAE form) |
| | | | <input type="checkbox"/> 4 - Other: _____ |
-
- | | | |
|---|---|--|
| Groin hematoma | <input type="checkbox"/> No <input type="checkbox"/> Yes: | fill out SAE form |
| Intubation (excluding intubation necessary for IAT) | <input type="checkbox"/> No <input type="checkbox"/> Yes: | fill out SAE form |
| Hemicraniectomy | <input type="checkbox"/> No <input type="checkbox"/> Yes: | fill out SAE form |
| External ventricular drain (EVD) | <input type="checkbox"/> No <input type="checkbox"/> Yes: | fill out SAE form |
| Major medical/surgical intervention | <input type="checkbox"/> No <input type="checkbox"/> Yes: | fill out SAE form and describe: _____ |

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 _____ |

Discharge

- Was the patient discharged No Yes: Date of discharge (dead or alive) ___/___/___
- Discharge destination:
- 0 - Patient died (**please fill out SAE form**)
 - 1 - Home
 - 2 - Other hospital (**transfer; please fill out transfer CRF**)
 - 3 - Geriatric rehabilitation center
 - 4 - Nursing home long stay
 - 5 - Rehabilitation center
 - 6 - Other, please specify: _____
- Name of discharge destination: _____

(S)AE Check at discharge – Intervention center

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

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

SERIOUS ADVERSE EVENT (SAE) CRF

General information	
Name investigator: _____	Signature investigator: _____
Date of report: ___/___/___ DD/MM/YYYY	
Description of SAE (in Dutch or English):	
<p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	
Date of SAE onset	
Date: ___/___/___ DD/MM/YYYY	
Neurological deterioration and/or neuroimaging	
Neurological deterioration of 4 points or more on NIHSS?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Neurological deterioration of 2 points or more on one NIHSS Item ?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Was there neuroimaging performed for this SAE/Neurological deterioration?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Serious Adverse Event category, please choose one:	SAE expected?
<input type="checkbox"/> 0 – Results in death <input type="checkbox"/> 1 – Life threatening (at the time of event) <input type="checkbox"/> 2 – Requires or prolongs hospitalization <input type="checkbox"/> 3 – Results in persistent or significant disability or incapacity <input type="checkbox"/> 4 – Other, please specify: _____ <input type="checkbox"/> 5 – Not listed above (i.e. not a serious adverse event)	<i>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 ischemic stroke.</i> If No: please report the unexpected SAE within 24 hours. <input type="checkbox"/> No <input type="checkbox"/> Yes
Select most likely cause of SAE, please choose one:	Was there another cause of (S)AE, you may choose multiple
<input type="checkbox"/> 0 – Stroke progression <input type="checkbox"/> 1 – New ischemic stroke: <input type="checkbox"/> Same <input type="checkbox"/> Different vascular territory <input type="checkbox"/> 2 – Intracranial hemorrhage <input type="checkbox"/> 3 – Extracranial hemorrhage <input type="checkbox"/> 4 – Cardiac ischemia <input type="checkbox"/> 5 – Allergic reaction <input type="checkbox"/> 6 – Pneumonia <input type="checkbox"/> 7 – Other infection, please specify: _____ <input type="checkbox"/> 8 – Other, please specify: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes: <input type="checkbox"/> 0 – Stroke progression <input type="checkbox"/> 1 – New ischemic stroke: <input type="checkbox"/> Same <input type="checkbox"/> Different vascular territory <input type="checkbox"/> 2 – Intracranial hemorrhage <input type="checkbox"/> 3 – Extracranial hemorrhage <input type="checkbox"/> 4 – Cardiac ischemia <input type="checkbox"/> 5 – Allergic reaction <input type="checkbox"/> 6 – Pneumonia <input type="checkbox"/> 7 – Other infection: _____ <input type="checkbox"/> 8 – Other, please specify: _____
Relationship with the study treatment	Actions regarding the study treatment:
<input type="checkbox"/> 0 – None <input type="checkbox"/> 1 – Unlikely <input type="checkbox"/> 2 – Possible <input type="checkbox"/> 3 – Probable <input type="checkbox"/> 4 – Definite	<input type="checkbox"/> 0 – None <input type="checkbox"/> 1 – Interrupted <input type="checkbox"/> 2 – Discontinued <input type="checkbox"/> 3 – Other, please specify: _____
Outcome	
<input type="checkbox"/> 0 – Resolved without sequela(e) date: ___/___/___ DD/MM/YYYY <input type="checkbox"/> 1 – Resolved with sequela(e) date: ___/___/___ DD/MM/YYYY and describe sequela(e): _____ <input type="checkbox"/> 2 – Ongoing (pending) _____ <input type="checkbox"/> 3 – Death date: ___/___/___ DD/MM/YYYY	

Additional (S)AE forms are available on the website: <https://mrclean-med.nl/documents.html>

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

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 de behandeling 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 van 3 maanden. 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 moeten 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/het infarct. Hieronder geven we enkele voorbeelden van SAE's.

Study number: 10128

Date of inclusion: 08/12/2017

Patient sticker/label

OR

Patient name: T. Jansen +

Patient ID: 00000

SERIOUS ADVERSE EVENT (SAE) CRF

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

General information	
Name investigator: Dr. C	Signature investigator: _____
Date of report: 10/12/2017	
Description of SAE (in Dutch or English):	
55-year-old female patient presented with right-sided hemiparesis and aphasia. The patient was allocated to the treatment xxx arm. The patient experienced clinical deterioration (increase NIHSS >2 points). CT-cerebrum revealed a midline shift, increase of edema, and expansion of infarcted territory on day 1. A decompressive hemicraniectomy was performed. No complications were noted during the operation.	
Date of SAE onset	
Date: 09/12/2017	
Neurological deterioration and/or neuroimaging	
Neurological deterioration of 4 points or more on NIHSS?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Neurological deterioration of 2 points or more on one NIHSS item?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Was there neuroimaging performed for this SAE/Neurological deterioration?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Serious Adverse Event category, please choose one:	
<input type="checkbox"/> 0 - Results in death	SAE expected? All SAEs are expected if this is one of the known side effects of the study treatment or one of the common (potentially) serious complications after ischemic stroke. If No, please report the unexpected SAE within 24 hours. <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
<input checked="" type="checkbox"/> 1 - Life threatening (at the time of event)	
<input type="checkbox"/> 2 - Requires or prolongs hospitalization	
<input type="checkbox"/> 3 - Results in persistent or significant disability or incapacity	
<input type="checkbox"/> 4 - Other, please specify: _____	
<input type="checkbox"/> 5 - Not listed above (i.e. not a serious adverse event)	
Select most likely cause of SAE, please choose one:	
<input checked="" type="checkbox"/> 0 - Stroke progression	Was there another cause of (S)AE, you may choose multiple <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes: <ul style="list-style-type: none"> <input type="checkbox"/> 0 - Stroke progression <input type="checkbox"/> 1 - New ischemic stroke: <ul style="list-style-type: none"> <input type="checkbox"/> Same <input type="checkbox"/> Different vascular territory <input type="checkbox"/> 2 - Intracranial hemorrhage <input type="checkbox"/> 3 - Extracranial hemorrhage <input type="checkbox"/> 4 - Cardiac ischemia <input type="checkbox"/> 5 - Allergic reaction <input type="checkbox"/> 6 - Pneumonia <input type="checkbox"/> 7 - Other infection, please specify: _____ <input type="checkbox"/> 8 - Other, please specify: _____
<input type="checkbox"/> 1 - New ischemic stroke: <ul style="list-style-type: none"> <input type="checkbox"/> Same <input type="checkbox"/> Different vascular territory 	
<input type="checkbox"/> 2 - Intracranial hemorrhage	
<input type="checkbox"/> 3 - Extracranial hemorrhage	
<input type="checkbox"/> 4 - Cardiac ischemia	
<input type="checkbox"/> 5 - Allergic reaction	
<input type="checkbox"/> 6 - Pneumonia	
<input type="checkbox"/> 7 - Other infection, please specify: _____	
<input type="checkbox"/> 8 - Other, please specify: _____	
Relationship with the study treatment	
<input type="checkbox"/> 0 - None	Actions regarding the study treatment: <input checked="" type="checkbox"/> 0 - None <input type="checkbox"/> 1 - Interrupted <input type="checkbox"/> 2 - Possible <input type="checkbox"/> 3 - Other, please specify: _____
<input type="checkbox"/> 1 - Unlikely	
<input type="checkbox"/> 2 - Possible	
<input type="checkbox"/> 3 - Probable	
<input type="checkbox"/> 4 - Definite	
Outcome	
<input type="checkbox"/> 0 - Resolved without sequela(e) date: ___/___/___ DD/MM/YYYY	Relationship with the study treatment <input checked="" type="checkbox"/> 0 - None <input type="checkbox"/> 1 - Interrupted <input type="checkbox"/> 2 - Possible <input type="checkbox"/> 3 - Probable <input type="checkbox"/> 4 - Definite
<input type="checkbox"/> 1 - Resolved with sequela(e) date: ___/___/___ DD/MM/YYYY and describe sequela(e): _____	
<input checked="" type="checkbox"/> 2 - Ongoing (pending) date: ___/___/___ DD/MM/YYYY	
<input type="checkbox"/> 3 - Death date: ___/___/___ DD/MM/YYYY	

CONTRAST

Study number: 20089

Date of inclusion: 16/12/2017

Patient sticker/label

OR

Patient name: A. van Berg +

Patient ID: 00000

SERIOUS ADVERSE EVENT (SAE) CRF

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

General information	
Name investigator: Dr. van de G.	Signature investigator: _____
Date of report: 24/12/2017	
Description of SAE (in Dutch or English):	
69-year-old male patient was allocated to the treatment (xxx) arm. Total NIHSS score was 16 points. IAT was without complications. The patient developed fever (T: 38.9°C) on day 4. Laboratory results showed elevated CRP values. X-thorax showed no signs of infiltration. This led to prolonged hospital stay.	
Date of SAE onset	
Date: 20/12/2017	
Neurological deterioration and/or neuroimaging	
Neurological deterioration of 4 points or more on NIHSS?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Neurological deterioration of 2 points or more on one NIHSS item?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Was there neuroimaging performed for this SAE/Neurological deterioration?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
Serious Adverse Event category, please choose one:	
<input type="checkbox"/> 0 - Results in death	SAE expected? All SAEs are expected if this is one of the known side effects of the study treatment or one of the common (potentially) serious complications after ischemic stroke. If No, please report the unexpected SAE within 24 hours. <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
<input type="checkbox"/> 1 - Life threatening (at the time of event)	
<input checked="" type="checkbox"/> 2 - Requires or prolongs hospitalization	
<input type="checkbox"/> 3 - Results in persistent or significant disability or incapacity	
<input type="checkbox"/> 4 - Other, please specify: _____	
<input type="checkbox"/> 5 - Not listed above (i.e. not a serious adverse event)	
Select most likely cause of SAE, please choose one:	
<input type="checkbox"/> 0 - Stroke progression	Was there another cause of (S)AE, you may choose multiple <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes: <ul style="list-style-type: none"> <input type="checkbox"/> 0 - Stroke progression <input type="checkbox"/> 1 - New ischemic stroke: <ul style="list-style-type: none"> <input type="checkbox"/> Same <input type="checkbox"/> Different vascular territory <input type="checkbox"/> 2 - Intracranial hemorrhage <input type="checkbox"/> 3 - Extracranial hemorrhage <input type="checkbox"/> 4 - Cardiac ischemia <input type="checkbox"/> 5 - Allergic reaction <input checked="" type="checkbox"/> 6 - Pneumonia <input type="checkbox"/> 7 - Other infection, please specify: _____ <input type="checkbox"/> 8 - Other, please specify: _____
<input type="checkbox"/> 1 - New ischemic stroke: <ul style="list-style-type: none"> <input type="checkbox"/> Same <input type="checkbox"/> Different vascular territory 	
<input type="checkbox"/> 2 - Intracranial hemorrhage	
<input type="checkbox"/> 3 - Extracranial hemorrhage	
<input type="checkbox"/> 4 - Cardiac ischemia	
<input type="checkbox"/> 5 - Allergic reaction	
<input checked="" type="checkbox"/> 6 - Pneumonia	
<input type="checkbox"/> 7 - Other infection, please specify: _____	
<input type="checkbox"/> 8 - Other, please specify: _____	
Relationship with the study treatment	
<input checked="" type="checkbox"/> 0 - None	Actions regarding the study treatment: <input checked="" type="checkbox"/> 0 - None <input type="checkbox"/> 1 - Interrupted <input type="checkbox"/> 2 - Possible <input type="checkbox"/> 3 - Probable <input type="checkbox"/> 4 - Definite
<input type="checkbox"/> 1 - Unlikely	
<input type="checkbox"/> 2 - Possible	
<input type="checkbox"/> 3 - Probable	
<input type="checkbox"/> 4 - Definite	
Outcome	
<input type="checkbox"/> 0 - Resolved without sequela(e) date: ___/___/___ DD/MM/YYYY	Relationship with the study treatment <input checked="" type="checkbox"/> 0 - None <input type="checkbox"/> 1 - Interrupted <input type="checkbox"/> 2 - Possible <input type="checkbox"/> 3 - Probable <input type="checkbox"/> 4 - Definite
<input type="checkbox"/> 1 - Resolved with sequela(e) date: ___/___/___ DD/MM/YYYY and describe sequela(e): _____	
<input checked="" type="checkbox"/> 2 - Ongoing (pending) date: ___/___/___ DD/MM/YYYY	
<input type="checkbox"/> 3 - Death date: ___/___/___ DD/MM/YYYY	

CONTRAST

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

CRFs Second hospital (transfer)

NIHSS at 5-7 days (or discharge, if earlier) – Second hospital (transfer)

Date of NIHSS assessment: ___/___/___

1A. Level of consciousness (LOC)

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

1B. LOC Questions

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

1C. LOC Commands

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

2. Best gaze

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

3. Visual

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

4. Facial palsy

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

5A. Motor left arm

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

5B. Motor right arm

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

6A. Motor left leg

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

6B. Motor right leg

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

7. Limb ataxia

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

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
- 9 – Intubated or other, explain: _____

11. Extinction and inattention

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

(S)AE Check at 5-7 days – Second hospital (transfer)

Did the patient experience one or more (serious) adverse event(s)?

No Yes (if Yes, please complete (S)AE form(s))

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

Discharge – Second hospital (transfer)

Neuroimaging in second hospital

Was there neuroimaging performed at your center? No Yes

Antithrombotic agents during hospital stay in second hospital

Any type of antithrombotic agents started? No Yes:

			<i>If applicable:</i>	
Acetylsalicylic acid/ carbasalate calcium	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date	___/___/___	Time ___:___ Stop date ___/___/___
Clopidogrel	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date	___/___/___	Time ___:___ Stop date ___/___/___
Dipyridamol	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date	___/___/___	Time ___:___ Stop date ___/___/___
Ticagrelor	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date	___/___/___	Time ___:___ Stop date ___/___/___
Prophylactic heparin	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date	___/___/___	Time ___:___ Stop date ___/___/___
Therapeutic heparin	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date	___/___/___	Time ___:___ Stop date ___/___/___
Vitamin K antagonist	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date	___/___/___	Time ___:___ Stop date ___/___/___
Direct oral anticoagulant (DOAC)	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date	___/___/___	Time ___:___ Stop date ___/___/___
Other: _____		Start date	___/___/___	Time ___:___ Stop date ___/___/___
Other: _____		Start date	___/___/___	Time ___:___ Stop date ___/___/___

Interventions and diagnoses during hospital stay in second hospital

Atrial fibrillation de novo	<input type="checkbox"/> No <input type="checkbox"/> Yes	Treatment:	<input type="checkbox"/> 0 - No
Aneurysma spurium	<input type="checkbox"/> No <input type="checkbox"/> Yes:		<input type="checkbox"/> 1 - (Pro)thrombin injection
			<input type="checkbox"/> 2 - Compression bandage
			<input type="checkbox"/> 3 - Surgical intervention (fill out SAE form)
			<input type="checkbox"/> 4 - Other: _____
Groin hematoma	<input type="checkbox"/> No <input type="checkbox"/> Yes:		fill out SAE form
Intubation (excluding intubation necessary for IAT)	<input type="checkbox"/> No <input type="checkbox"/> Yes:		fill out SAE form
Hemicraniectomy	<input type="checkbox"/> No <input type="checkbox"/> Yes:		fill out SAE form
External ventricular drain (EVD)	<input type="checkbox"/> No <input type="checkbox"/> Yes:		fill out SAE form
Major medical/surgical intervention	<input type="checkbox"/> No <input type="checkbox"/> Yes:		fill out SAE form and describe: _____

Admission in second hospital

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	_____

Discharge (destination after second hospital)

Was the patient discharged No Yes: _____

Date of discharge (dead or alive) ___/___/___

Discharge destination:

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

1 - Home

2 - Other hospital

3 - Geriatric rehabilitation center

4 - Nursing home long stay

5 - Rehabilitation center

6 - Other, please specify: _____

Name of discharge destination: _____

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

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

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

SERIOUS ADVERSE EVENT (SAE) CRF**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

Neurological deterioration and/or neuroimaging

Neurological deterioration of 4 points or more on NIHSS? No Yes
 Neurological deterioration of 2 points or more on **one NIHSS Item**? No Yes
 Was there neuroimaging performed for this SAE/Neurological deterioration? No Yes

Serious Adverse Event category, please choose one:

- 0 – Results in death
 1 – Life threatening (at the time of event)
 2 – Requires or prolongs 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 ischemic stroke.
If No: please report the unexpected SAE within 24 hours.

 No Yes**Select most likely cause of SAE, please choose one:**

- 0 – Stroke progression
 1 – New ischemic stroke:
 Same Different vascular territory
 2 – Intracranial hemorrhage
 3 – Extracranial hemorrhage
 4 – Cardiac ischemia
 5 – Allergic reaction
 6 – Pneumonia
 7 – Other infection, please specify: _____
 8 – Other, please specify: _____

Was there another cause of (S)AE, you may choose multiple

- No Yes:
 0 – Stroke progression
 1 – New ischemic stroke:
 Same Different vascular territory
 2 – Intracranial hemorrhage
 3 – Extracranial hemorrhage
 4 – Cardiac ischemia
 5 – Allergic reaction
 6 – Pneumonia
 7 – Other infection: _____
 8 – Other, please specify: _____

Relationship with the study treatment

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

Actions regarding the study treatment:

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

Outcome

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

Additional (S)AE forms are available on the website: <https://mrclean-med.nl/documents.html>

Study number:

Date of inclusion: ___/___/___

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

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 de behandeling 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 van 3 maanden. 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 moeten 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/het infarct. Hieronder geven we enkele voorbeelden van SAE's.

Study number: Date of inclusion: 08/12/2017

Patient sticker/label
OR
Patient name: T. Jansen +
Patient ID: 00000

SERIOUS ADVERSE EVENT (SAE) CRF

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

General information	
Name investigator: Dr. C	Signature investigator: _____
Date of report: 10/12/2017	
Description of SAE (in Dutch or English):	
55-year-old female patient presented with right-sided hemiparesis and aphasia. The patient was allocated to the treatment xxx arm. The patient experienced clinical deterioration (increase NIHSS >2 points). CT-cerebrum revealed a midline shift, increase of edema, and expansion of infarcted territory on day 1. A decompressive hemicraniectomy was performed. No complications were noted during the operation.	
Date of SAE onset	
Date: 09/12/2017	
Neurological deterioration and/or neuroimaging	
Neurological deterioration of 4 points or more on NIHSS? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	Neurological deterioration of 2 points or more on one NIHSS item? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Was there neuroimaging performed for this SAE/Neurological deterioration? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	
Serious Adverse Event category, please choose one:	
<input type="checkbox"/> 0 - Results in death <input checked="" type="checkbox"/> 1 - Life threatening (at the time of event) <input type="checkbox"/> 2 - Requires or prolongs hospitalization <input type="checkbox"/> 3 - Results in persistent or significant disability or incapacity <input type="checkbox"/> 4 - Other, please specify: _____ <input type="checkbox"/> 5 - Not listed above (i.e. not a serious adverse event)	
SAE expected?	
<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes <small>All SAEs are expected if this is one of the known side effects of the study treatment or one of the common (potentially) serious complications after ischemic stroke. If No, please report the unexpected SAE within 24 hours.</small>	
Select most likely cause of SAE, please choose one:	
<input checked="" type="checkbox"/> 0 - Stroke progression <input type="checkbox"/> 1 - New ischemic stroke: <input type="checkbox"/> Same <input type="checkbox"/> Different vascular territory <input type="checkbox"/> 2 - Intracranial hemorrhage <input type="checkbox"/> 3 - Extracranial hemorrhage <input type="checkbox"/> 4 - Cardiac ischemia <input type="checkbox"/> 5 - Allergic reaction <input type="checkbox"/> 6 - Pneumonia <input type="checkbox"/> 7 - Other infection, please specify: _____ <input type="checkbox"/> 8 - Other, please specify: _____	
Was there another cause of (S)AE, you may choose multiple	
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 0 - Stroke progression <input type="checkbox"/> 1 - New ischemic stroke: <input type="checkbox"/> Same <input type="checkbox"/> Different vascular territory <input type="checkbox"/> 2 - Intracranial hemorrhage <input type="checkbox"/> 3 - Extracranial hemorrhage <input type="checkbox"/> 4 - Cardiac ischemia <input type="checkbox"/> 5 - Allergic reaction <input type="checkbox"/> 6 - Pneumonia <input type="checkbox"/> 7 - Other infection, please specify: _____ <input type="checkbox"/> 8 - Other, please specify: _____	
Relationship with the study treatment	
<input type="checkbox"/> 0 - None <input type="checkbox"/> 1 - Unlikely <input type="checkbox"/> 2 - Possible <input type="checkbox"/> 3 - Probable <input type="checkbox"/> 4 - Definite	
Actions regarding the study treatment:	
<input checked="" type="checkbox"/> 0 - None <input type="checkbox"/> 1 - Interrupted <input type="checkbox"/> 2 - Discontinued <input type="checkbox"/> 3 - Other, please specify: _____	
Outcome	
<input type="checkbox"/> 0 - Resolved without sequela(e) date: ___/___/___ DD/MM/YYYY <input type="checkbox"/> 1 - Resolved with sequela(e) date: ___/___/___ DD/MM/YYYY and describe sequela(e): _____ <input checked="" type="checkbox"/> 2 - Ongoing (pending) date: ___/___/___ DD/MM/YYYY <input type="checkbox"/> 3 - Death date: ___/___/___ DD/MM/YYYY	

CONTRAST

Study number: Date of inclusion: 16/12/2017

Patient sticker/label
OR
Patient name: A. van Berg +
Patient ID: 00000

SERIOUS ADVERSE EVENT (SAE) CRF

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

General information	
Name investigator: Dr. van de G.	Signature investigator: _____
Date of report: 24/12/2017	
Description of SAE (in Dutch or English):	
69-year-old male patient was allocated to the treatment (xxx) arm. Total NIHSS score was 16 points. IAT was without complications. The patient developed fever (T: 38.9°C) on day 4. Laboratory results showed elevated CRP values. X-thorax showed no signs of infiltration. This led to prolonged hospital stay.	
Date of SAE onset	
Date: 20/12/2017	
Neurological deterioration and/or neuroimaging	
Neurological deterioration of 4 points or more on NIHSS? <input type="checkbox"/> No <input type="checkbox"/> Yes	Neurological deterioration of 2 points or more on one NIHSS item? <input type="checkbox"/> No <input type="checkbox"/> Yes
Was there neuroimaging performed for this SAE/Neurological deterioration? <input type="checkbox"/> No <input type="checkbox"/> Yes	
Serious Adverse Event category, please choose one:	
<input type="checkbox"/> 0 - Results in death <input type="checkbox"/> 1 - Life threatening (at the time of event) <input checked="" type="checkbox"/> 2 - Requires or prolongs hospitalization <input type="checkbox"/> 3 - Results in persistent or significant disability or incapacity <input type="checkbox"/> 4 - Other, please specify: _____ <input type="checkbox"/> 5 - Not listed above (i.e. not a serious adverse event)	
SAE expected?	
<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes <small>All SAEs are expected if this is one of the known side effects of the study treatment or one of the common (potentially) serious complications after ischemic stroke. If No, please report the unexpected SAE within 24 hours.</small>	
Select most likely cause of SAE, please choose one:	
<input type="checkbox"/> 0 - Stroke progression <input type="checkbox"/> 1 - New ischemic stroke: <input type="checkbox"/> Same <input type="checkbox"/> Different vascular territory <input type="checkbox"/> 2 - Intracranial hemorrhage <input type="checkbox"/> 3 - Extracranial hemorrhage <input type="checkbox"/> 4 - Cardiac ischemia <input type="checkbox"/> 5 - Allergic reaction <input checked="" type="checkbox"/> 6 - Pneumonia <input type="checkbox"/> 7 - Other infection, please specify: _____ <input type="checkbox"/> 8 - Other, please specify: _____	
Was there another cause of (S)AE, you may choose multiple	
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 0 - Stroke progression <input type="checkbox"/> 1 - New ischemic stroke: <input type="checkbox"/> Same <input type="checkbox"/> Different vascular territory <input type="checkbox"/> 2 - Intracranial hemorrhage <input type="checkbox"/> 3 - Extracranial hemorrhage <input type="checkbox"/> 4 - Cardiac ischemia <input type="checkbox"/> 5 - Allergic reaction <input type="checkbox"/> 6 - Pneumonia <input type="checkbox"/> 7 - Other infection, please specify: _____ <input type="checkbox"/> 8 - Other, please specify: _____	
Relationship with the study treatment	
<input checked="" type="checkbox"/> 0 - None <input type="checkbox"/> 1 - Unlikely <input type="checkbox"/> 2 - Possible <input type="checkbox"/> 3 - Probable <input type="checkbox"/> 4 - Definite	
Actions regarding the study treatment:	
<input checked="" type="checkbox"/> 0 - None <input type="checkbox"/> 1 - Interrupted <input type="checkbox"/> 2 - Discontinued <input type="checkbox"/> 3 - Other, please specify: _____	
Outcome	
<input type="checkbox"/> 0 - Resolved without sequela(e) date: ___/___/___ DD/MM/YYYY <input type="checkbox"/> 1 - Resolved with sequela(e) date: ___/___/___ DD/MM/YYYY and describe sequela(e): _____ <input checked="" type="checkbox"/> 2 - Ongoing (pending) date: ___/___/___ DD/MM/YYYY <input type="checkbox"/> 3 - Death date: ___/___/___ DD/MM/YYYY	

CONTRAST