MR CLEAN–NO IV:

Intravenous treatment followed by intra-arterial treatment versus direct intra-arterial treatment for acute ischemic stroke caused by a proximal intracranial occlusion.

Case Report Forms (CRFs) ON PAPER

Version 1.1, 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-NO IV team
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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	Motor	Verbal
□ **4 -** Opens eyes spontaneously	□ **6 -** Obeys commands	□ **5 -** Oriented/converses normally
□ **3 -** Opens eyes in response to voice	□ **5 -** Localizes painful stimuli	□ **4 -** Confused/disoriented
□ **2** - Opens eyes in resp. to painful stimuli	□ **4 -** Flexion/withdrawal to painful stimuli	□ **3 -** Utters inappropriate words
□ **1** - Does not open eyes	□ **3 -** Abnormal flexion to painful stimuli	□ **2 -** Incomprehensible sounds
	□ **2 -** Extension to painful stimuli	□ **1 -** Makes no sounds
	□ **1 -** Makes no movements	

Vital parameters - first intra-hospital/ER: *Round numbers except for body temp (1 decimal)*

Systolic blood pressure	_____ mm Hg	Diastolic blood pressure	_____ mm Hg
Heart rate	_____ /min	Body temperature	__ __ . __ ^{0}C
Height	_____ cm	Weight	_____ kg

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

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

NIHSS at baseline

1A. Level of consciousness (LOC)	1B. LOC Questions
□ **0** – Alert	□ **0** – Answers both questions correctly
□ **1** – Not alert, but arousable	□ **1** – Answers one question correctly
□ **2** – Not alert, requires repeated stimulation	□ **2** – Answers neither questions correctly
□ **3** – Comatose	
1C. LOC Commands	**2. Best gaze**
□ **0** – Performs both tasks correctly	□ **0** – Normal
□ **1 –** Performs one task correctly	□ **1** – Partial gaze palsy
□ **2** – Performs neither tasks correctly	□ **2** – Forced deviation
3 Visual	**4. Facial palsy**
□ **0** – No visual loss	□ **0** – Normal
□ **1** – Partial hemianopia	□ **1** – Minor paralysis
□ **2** – Complete hemianopia	□ **2** – Partial paralysis
□ **3** – Bilateral hemianopia	□ **3** – Complete paralysis
5A. Motor left arm	**5B. Motor right arm**
□ **0** – No drift	□ **0** – No drift
□ **1** – Drift	□ **1** – Drift
□ **2** – Some effort against gravity	□ **2** – Some effort against gravity
□ **3** – No effort against gravity	□ **3** – No effort against gravity
□ **4** – No movement	□ **4** – No movement
□ **9** – Untestable, explain reason: _____	□ **9** – Untestable, explain reason: _____
6A. Motor left leg	**6B. Motor right leg**
□ **0** – No drift	□ **0** – No drift
□ **1** – Drift	□ **1** – Drift
□ **2** – Some effort against gravity	□ **2** – Some effort against gravity
□ **3** – No effort against gravity	□ **3** – No effort against gravity
□ **4** – No movement	□ **4** – No movement
□ **9** – Untestable, explain reason: _____	□ **9** – Untestable, explain reason: _____
7. Limb ataxia	**8. Sensory**
□ **0** – Absent	□ **0** – Normal
□ **1** – Present in one limb	□ **1** – Mild to moderate sensory loss
□ **2** – Present in two limbs	□ **2** – Severe or total sensory loss
9. Best language	**10. Dysarthria**
□ **0** – No aphasia (normal)	□ **0** – Normal
□ **1** – Mild to moderate aphasia	□ **1** – Mild to moderate dysarthria
□ **2** – Severe aphasia	□ **2** – Severe dysarthria
□ **3** – Mute, global aphasia	□ **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-NO IV STUDY TREATMENT CRF

If randomized to IVT+IAT	
Planned IV alteplase dose	_____ mg
IV alteplase administered	□ No **(specify below)** □ Yes:
If Yes:	
Time of IV alteplase bolus	____:____ hh:mm
Was the IV alteplase pump stopped early	□ No □ Yes: amount left in pump: _____ ml, and explain why the pump was stopped early: _____ _____
If randomized to direct IAT	
Escape IV alteplase administered	□ No □ Yes **(specify below):**
If Yes:	
Time of bolus escape IV alteplase	____:____ hh:mm
Planned escape IV alteplase dose	_____ mg
Received escape IV alteplase dose	_____ mg
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)	1B. LOC Questions
□ **0** – Alert	□ **0** – Answers both questions correctly
□ **1** – Not alert, but arousable	□ **1** – Answers one question correctly
□ **2** – Not alert, requires repeated stimulation	□ **2** – Answers neither questions correctly
□ **3** – Comatose	

1C. LOC Commands	2. Best gaze
□ **0** – Performs both tasks correctly	□ **0** – Normal
□ **1 –** Performs one task correctly	□ **1** – Partial gaze palsy
□ **2** – Performs neither tasks correctly	□ **2** – Forced deviation

3. Visual	4. Facial palsy
□ **0** – No visual loss	□ **0** – Normal
□ **1** – Partial hemianopia	□ **1** – Minor paralysis
□ **2** – Complete hemianopia	□ **2** – Partial paralysis
□ **3** – Bilateral hemianopia	□ **3** – Complete paralysis

5A. Motor left arm	5B. Motor right arm
□ **0** – No drift	□ **0** – No drift
□ **1** – Drift	□ **1** – Drift
□ **2** – Some effort against gravity	□ **2** – Some effort against gravity
□ **3** – No effort against gravity	□ **3** – No effort against gravity
□ **4** – No movement	□ **4** – No movement
□ **9** – Untestable, explain reason: _____	□ **9** – Untestable, explain reason: _____

6A. Motor left leg	6B. Motor right leg
□ **0** – No drift	□ **0** – No drift
□ **1** – Drift	□ **1** – Drift
□ **2** – Some effort against gravity	□ **2** – Some effort against gravity
□ **3** – No effort against gravity	□ **3** – No effort against gravity
□ **4** – No movement	□ **4** – No movement
□ **9** – Untestable, explain reason: _____	□ **9** – Untestable, explain reason: _____

7. Limb ataxia	8. Sensory
□ **0** – Absent	□ **0** – Normal
□ **1** – Present in one limb	□ **1** – Mild to moderate sensory loss
□ **2** – Present in two limbs	□ **2** – Severe or total sensory loss

9. Best language	10. Dysarthria
□ **0** – No aphasia (normal)	□ **0** – Normal
□ **1** – Mild to moderate aphasia	□ **1** – Mild to moderate dysarthria
□ **2** – Severe aphasia	□ **2** – Severe dysarthria
□ **3** – Mute, global aphasia	□ 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	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Clopidogrel	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Dipyridamol	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Ticagrelor	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Prophylactic heparin	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Therapeutic heparin	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Vitamin K antagonist	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Direct oral anticoagulant (DOAC)	□ No □ 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 □ No □ Yes

Aneurysma spurium □ No □ Yes: Treatment:
- □ **0** - No
- □ **1** - (Pro)thrombin injection
- □ **2** - Compression bandage
- □ **3** - Surgical intervention **(fill out SAE form)**
- □ **4** - Other: _____

Groin hematoma	□ No □ Yes:	**fill out SAE form**
Intubation (excluding intubation necessary for IAT)	□ No □ Yes:	**fill out SAE form**
Hemicraniectomy	□ No □ Yes:	**fill out SAE form**
External ventricular drain (EVD)	□ No □ Yes:	**fill out SAE form**
Major medical/surgical intervention	□ No □ Yes:	**fill out SAE form** and describe: _____ _____

Admission

Was the patient admitted to the:		Total number of days in:	
- ICU	□ No □ Yes	- ICU	_____
- Medium care?	□ No □ Yes	- Medium care	_____
- Stroke Unit?	□ No □ Yes	- Stroke Unit	_____

Discharge

Was the patient discharged □ No □ Yes: Date of discharge (dead or alive) __ /__ /____

Discharge destination:
- □ **0** - Patient died **(fill out SAE form)**
- □ **1** - Home
- □ **2** - Other hospital **(transfer; 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):

_____
_____
_____
_____
_____
_____
_____
_____

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-noiv.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 hemi paralysis 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? ▫ No **X** Yes
Neurological deterioration of 2 points or more on **one NIHSS Item**? ▫ No **X** Yes
Was there neuroimaging performed for this SAE/Neurological deterioration? ▫ No **X** Yes

Serious Adverse Event category, please choose one:

▫ **0** – Results in death
X 1 – Life threatening (at the time of event)
▫ **2** – Requires 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 **X** Yes

Select most likely cause of SAE, please choose one:

X 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

X 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
X 1 – Unlikely
▫ **2** – Possible
▫ **3** – Probable
▫ **4** – Definite

Actions regarding the study treatment:

X 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): _____
X 2 – Ongoing (pending)
▫ **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? **X** No ▫ Yes
Neurological deterioration of 2 points or more on **one NIHSS Item**? **X** No ▫ Yes
Was there neuroimaging performed for this SAE/Neurological deterioration? **X** No ▫ Yes

Serious Adverse Event category, please choose one:

▫ **0** – Results in death
▫ **1** – Life threatening (at the time of event)
X 2 – Requires 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 **X** 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
X 6 – Pneumonia
▫ **7** – Other infection, please specify: _____
▫ **8** – Other, please specify: _____

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

X 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

X 0 – None
▫ **1** – Unlikely
▫ **2** – Possible
▫ **3** – Probable
▫ **4** – Definite

Actions regarding the study treatment:

X 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): _____
X **2** – Ongoing (pending)
▫ **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:

		If applicable:
Acetylsalicylic acid/ carbasalate calcium	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Clopidogrel	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Dipyridamol	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Ticagrelor	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Prophylactic heparin	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Therapeutic heparin	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Vitamin K antagonist	□ No □ Yes	Start date __ /__ /____ Time __:__ Stop date __ /__ /____
Direct oral anticoagulant (DOAC)	□ No □ 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 □ No □ Yes

Aneurysma spurium □ No □ Yes: Treatment:
- □ **0** - No
- □ **1** - (Pro)thrombin injection
- □ **2** - Compression bandage
- □ **3** - Surgical intervention **(fill out SAE form)**
- □ **4** - Other: _____

Groin hematoma □ No □ Yes: **fill out SAE form**

Intubation (excluding intubation necessary for IAT) □ No □ Yes: **fill out SAE form**

Hemicraniectomy □ No □ Yes: **fill out SAE form**

External ventricular drain (EVD) □ No □ Yes: **fill out SAE form**

Major medical/surgical intervention □ No □ Yes: **fill out SAE form** and describe: _____
_____

Admission in second hospital

Was the patient admitted to the:
- ICU □ No □ Yes
- Medium care? □ No □ Yes
- Stroke Unit? □ No □ Yes

Total number of days in:
- ICU _____
- Medium care _____
- Stroke Unit _____

Discharge (destination after second hospital)

Was the patient discharged □ No □ Yes: Date of discharge (dead or alive) __ /__ /____

Discharge destination:
- □ **0** - Patient died **(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:	SAE **expected**?
□ **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)	*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:	Was there **another cause** of (S)AE, you may choose multiple
□ **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: _____	□ 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	**Actions** regarding the study treatment:
□ **0** – None □ **1** – Unlikely □ **2** – Possible □ **3** – Probable □ **4** – Definite	□ **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-noiv.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 hemi paralysis 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? ▫ No **X** Yes

Neurological deterioration of 2 points or more on **one NIHSS Item**? ▫ No **X** Yes

Was there neuroimaging performed for this SAE/Neurological deterioration? ▫ No **X** Yes

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

▫ **0** – Results in death
X 1 – Life threatening (at the time of event)
▫ **2** – Requires 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 **X** Yes

Select **most likely cause of** SAE, please choose one:

X 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

X 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
X 1 – Unlikely
▫ **2** – Possible
▫ **3** – Probable
▫ **4** – Definite

Actions regarding the study treatment:

X 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): _____
X 2 – Ongoing (pending) _____
▫ **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? **X** No ▫ Yes

Neurological deterioration of 2 points or more on **one NIHSS Item**? **X** No ▫ Yes

Was there neuroimaging performed for this SAE/Neurological deterioration? **X** No ▫ Yes

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

▫ **0** – Results in death
▫ **1** – Life threatening (at the time of event)
X 2 – Requires 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 **X** 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
X 6 – Pneumonia
▫ **7** – Other infection, please specify: _____
▫ **8** – Other, please specify: _____

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

X 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

X 0 – None
▫ **1** – Unlikely
▫ **2** – Possible
▫ **3** – Probable
▫ **4** – Definite

Actions regarding the study treatment:

X 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): _____
X 2 – Ongoing (pending) _____
▫ **3** – Death date: __/__/____ DD/MM/YYYY

CONTRAST