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

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

SERIOUS ADVERSE EVENT (SAE) CRF

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

General information

Name investigator: _____ Signature investigator:

Date of report: ____/____/_____ DD/MM/YYYY

Description of SAE (in Dutch or English):

_____
_____
_____
_____
_____
_____
_____
_____

Date of SAE onset

Date: ____/____/_____ DD/MM/YYYY

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 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

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