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

Dutch ICH Surgery Trial (DIST): SERIOUS ADVERSE EVENTS (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

Neuroimaging

Was there neuroimaging performed for this SAE? □ No □ Yes

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

□ **0** – Results in death
□ **1** – Life threatening (at the time of event)
□ **2** – Requires prolonged 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 ICH.

If No: please report the unexpected SAE within 24 hours.

□ No □ Yes

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

□ **0** – Intracerebral hemorrhage progression
□ **1** – Intracerebral hemorrhage (other location, symptomatic)
□ **2 –** Ischemic stroke
□ **3 –** Subdural/epidural hematoma
□ **4** – Hydrocephalus
□ **5** – Surgical device deficiency
□ **6 –** Extracranial hemorrhage (e.g. gastro-intestinal)
□ **7 –** Cardiac ischemia
□ **8 –** Allergic reaction
□ **9 –** Pneumonia
□ **10-** Intracranial infection
□ **11-** Postoperative site infection
□ **12-** Other infection: _____
□ **13-** Deep venous thrombosis or pulmonary embolism
□ **14-** Seizure(s)
□ **15-** Other: _____

Was there **another cause** for SAE, you may choose multiple

□ No □ Yes:
- □ **0** – Intracerebral hemorrhage progression
- □ 1 – Intracerebral hemorrhage (other location, symptomatic)
- □ **2** – Ischemic stroke
- □ **3** – Subdural/epidural hematoma
- □ **4** – Hydrocephalus
- □ **5** – Surgical device deficiency
- □ **6** – Extracranial hemorrhage (e.g. gastro-intestinal)
- □ **7** – Cardiac ischemia
- □ **8** – Allergic reaction
- □ **9** – Pneumonia
- □ **10**- Intracranial infection
- □ **11**- Postoperative site infection
- □ **12**- Other infection: _____
- □ **13**- Deep venous thrombosis or pulmonary embolism
- □ **14**- Seizure(s)
- □ **15**- Other: _____

Relationship with the study procedures

□ **0** - None
□ **1** - Unlikely
□ **2** - Possible
□ **3** - Probable
□ **4** - Definite

Actions regarding study participation

□ **0** - None
□ **1** - Interrupted
□ **2** - Withdrawn
□ **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: dutch-ich.nl

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

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 het onderzoek 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. 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 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/de bloeding. Hieronder geven we enkele voorbeelden van SAE's.

Study number: 20103 Date of inclusion: 10 / 09 / 2022

Dutch ICH Surgery Trial (DIST): SERIOUS ADVERSE EVENTS (SAE) CRF

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

General information

Name investigator: Dr. A. Janssen Signature investigator:

Date of report: 12 / 09 / 2022

Description of SAE (in Dutch or English):

72-year-old female patient with a deep intracerebral hemorrhage with intraventricular extension, allocated to the control arm. After admission, the patient experienced gradual impairment of consciousness. CT-cerebrum revealed progressive ventricular enlargement, with no evidence of hematoma expansion on day 1. A right frontal EVD was inserted, which demonstrated a high opening pressure. After EVD insertion, a significant improvement in the patient's clinical condition was noted.

Date of SAE onset

Date: 11 / 09 / 2022

Neuroimaging

Was there neuroimaging performed for this SAE? □ 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 prolonged 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 ICH.

If No: please report the unexpected SAE within 24 hours.

□ No x Yes

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

- □ **0** – Intracerebral hemorrhage progression
- □ **1** – Intracerebral hemorrhage (other location, symptomatic)
- □ **2** – Ischemic stroke
- □ **3** – Subdural/epidural hematoma
- x **4** – Hydrocephalus
- □ **5** – Surgical device deficiency
- □ **6** – Extracranial hemorrhage (e.g. gastro-intestinal)
- □ **7** – Cardiac ischemia
- □ **8** – Allergic reaction
- □ **9** – Pneumonia
- □ **10**- Intracranial infection
- □ **11**- Postoperative site infection
- □ **12**- Other infection: _____
- □ **13**- Deep venous thrombosis or pulmonary embolism
- □ **14**- Seizure(s)
- □ **15**- Other: _____

Was there **another cause** for SAE, you may choose multiple

x No □ Yes:

- □ **0** – Intracerebral hemorrhage progression
- □ **1** – Intracerebral hemorrhage (other location, symptomatic)
- □ **2** – Ischemic stroke
- □ **3** – Subdural/epidural hematoma
- □ **4** – Hydrocephalus
- □ **5** – Surgical device deficiency
- □ **6** – Extracranial hemorrhage (e.g. gastro-intestinal)
- □ **7** – Cardiac ischemia
- □ **8** – Allergic reaction
- □ **9** – Pneumonia
- □ **10**- Intracranial infection
- □ **11**- Postoperative site infection
- □ **12**- Other infection: _____
- □ **13**- Deep venous thrombosis or pulmonary embolism
- □ **14**- Seizure(s)
- □ **15**- Other: _____

Relationship with the study procedures

- x **0** - None
- □ **1** - Unlikely
- □ **2** - Possible
- □ **3** - Probable
- □ **4** - Definite

Actions regarding study participation

- x **0** - None
- □ **1** - Interrupted
- □ **2** - Withdrawn
- □ **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

Additional (S)AE forms are available on the website: dutch-ich.nl

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Study number: 20381 Date of inclusion: 06 / 10 / 2022

Dutch ICH Surgery Trial (DIST): SERIOUS ADVERSE EVENTS (SAE) CRF

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

General information

Name investigator: Dr. B. de Vries Signature investigator:

Date of report: 15 / 10 / 2022

Description of SAE (in Dutch or English):

81-year-old male patient with a lobar intracerebral hemorrhage, allocated to the surgical arm. Surgery was without complications. Patient developed fever (T 39.2 °C) on day 5. Laboratory results showed elevated inflammatory markers. X-thorax showed right lower lobe infiltrate suggestive of pneumonia, for which treatment with amoxicillin/clavulanic acid was started. This led to prolonged hospital stay.

Date of SAE onset

Date: 11 / 10 / 2022

Neuroimaging

Was there neuroimaging performed for this SAE? 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 prolonged 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 ICH.

If No: please report the unexpected SAE within 24 hours.

□ No x Yes

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

- □ **0** – Intracerebral hemorrhage progression
- □ **1** – Intracerebral hemorrhage (other location, symptomatic)
- □ **2** – Ischemic stroke
- □ **3** – Subdural/epidural hematoma
- □ **4** – Hydrocephalus
- □ **5** – Surgical device deficiency
- □ **6** – Extracranial hemorrhage (e.g. gastro-intestinal)
- □ **7** – Cardiac ischemia
- □ **8** – Allergic reaction
- x **9** – Pneumonia
- □ **10**- Intracranial infection
- □ **11**- Postoperative site infection
- □ **12**- Other infection: _____
- □ **13**- Deep venous thrombosis or pulmonary embolism
- □ **14**- Seizure(s)
- □ **15**- Other: _____

Was there **another cause** for SAE, you may choose multiple

x No □ Yes:

- □ **0** – Intracerebral hemorrhage progression
- □ **1** – Intracerebral hemorrhage (other location, symptomatic)
- □ **2** – Ischemic stroke
- □ **3** – Subdural/epidural hematoma
- □ **4** – Hydrocephalus
- □ **5** – Surgical device deficiency
- □ **6** – Extracranial hemorrhage (e.g. gastro-intestinal)
- □ **7** – Cardiac ischemia
- □ **8** – Allergic reaction
- □ **9** – Pneumonia
- □ **10**- Intracranial infection
- □ **11**- Postoperative site infection
- □ **12**- Other infection: _____
- □ **13**- Deep venous thrombosis or pulmonary embolism
- □ **14**- Seizure(s)
- □ **15**- Other: _____

Relationship with the study procedures

- □ **0** - None
- x **1** - Unlikely
- □ **2** - Possible
- □ **3** - Probable
- □ **4** - Definite

Actions regarding study participation

- x **0** - None
- □ **1** - Interrupted
- □ **2** - Withdrawn
- □ **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

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