

Randomisation

Please fill in this form and then enter data on www.statich.no. If the patient is eligible for the trial, the computer will allocate treatment to the patient (“anticoagulant treatment”, or “no anticoagulant treatment”).

1. Eligibility checklist for STATICH-Anticoagulants

| | Yes | No |
|--|--------------------------|--------------------------|
| Is the patient eligible for STATICH-Anticoagulants (i.e. patient has atrial fibrillation/flutter and fulfils criteria below)? | <input type="checkbox"/> | <input type="checkbox"/> |
| Inclusion criteria: <ul style="list-style-type: none"> Age ≥18 years Spontaneous, primary intracerebral haemorrhage (ICH), and time since onset minimum 1 day (i.e. no preceding traumatic brain injury, and no “secondary” or underlying structural cause) Patient has atrial fibrillation /flutter (paroxysmal, persistent, or permanent), and has indication for anticoagulant drug Consent from the patient or their representative CT (or MRI for patients in MRI sub-study) is performed before randomisation Exclusion criteria: <ul style="list-style-type: none"> Clear indication for anticoagulant treatment (e.g. prosthetic heart valves) Clear contraindication for anticoagulant treatment Patient is pregnant or breastfeeding, or is not using contraception methods (if of childbearing potential) For patients in MRI sub-study: Contraindications for brain MRI Malignancy with life expectancy less than 2 years | | |

2. Please provide the details of the patient*

| | | | | |
|---|---|--|------------|---|
| Centre name | | <i>or:</i> | Centre no. | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| Investigator’s name | | If you have a label with the patient’s full name and address, please stick it here | | |
| Patient name | | | | |
| Date of birth | <input type="text"/> / <input type="text"/> / <input type="text"/> dd/mm/yy | | | |
| Gender | <input type="checkbox"/> Male <input type="checkbox"/> Female | | | |
| Name of GP or medical center | | Tel. no. | | |
| Name of nearest relative | | Tel. no. | | |
| *Only patient initials, gender and year of birth will be requested in the electronic CRF (on the web portal). The remaining information will be requested after randomisation, and shall be sent to the STATICH Coordinating Centre via ordinary/postal mail. | | | | |

3. Living arrangement and functional status before the qualifying ICH

| | | |
|---|--------------------------|--------------------------|
| Living arrangement | <input type="checkbox"/> | Living alone |
| | <input type="checkbox"/> | Living with someone else |
| | <input type="checkbox"/> | Living in an institution |
| | <input type="checkbox"/> | Other |
| Did the patient require assistance from anyone to undertake activities of daily living (e.g. walking, showering, toileting, dressing, feeding)? | <input type="checkbox"/> | <input type="checkbox"/> |
| | Yes | No |

4. Ischaemic vascular disease before randomisation

| | Yes | No | Unknown |
|--|--------------------------|--------------------------|--------------------------|
| Ischaemic heart disease (e.g. myocardial infarction, bypass surgery, stenting) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Peripheral arterial disease | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Symptomatic deep vein thrombosis or pulmonary embolus | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Transient ischaemic attack | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Ischaemic stroke | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Other, please specify: | | | |
| Did any of these events take place <i>after</i> the qualifying ICH? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes: Please specify: | | | |

5. Other diseases/conditions before randomisation

| | Yes | No | Unknown |
|--|--------------------------|--------------------------|--------------------------|
| Atrial fibrillation | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes: <input type="checkbox"/> Paroxysmal <input type="checkbox"/> Persistent <input type="checkbox"/> Permanent | | | |
| Atrial flutter | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes: <input type="checkbox"/> Paroxysmal <input type="checkbox"/> Persistent <input type="checkbox"/> Permanent | | | |
| Congestive cardiac failure | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Diabetes mellitus | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Renal failure | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes: Renal failure requiring dialysis? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Previous renal transplantation? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Prior intracerebral haemorrhage (i.e. before the ICH qualifying for STATICH) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Prior other intracranial haemorrhage (subarachnoid, subdural, extradural) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Prior gastrointestinal haemorrhage | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Prior other extracranial haemorrhage | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Hypertension or treatment for hypertension | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes: Uncontrolled blood pressure? (systolic BP > 160 mm Hg) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Alcohol consumption of 8 or more alcoholic drinks per week | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Use of vitamin K antagonist (e.g. warfarin) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes: Labile INR? (time in therapeutic range <60%) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Liver disease (cirrhosis or bilirubin >2 x, and liver transferases >3 x upper normal limit) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Anaemia | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Use of NSAIDS | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

6. Use of anticoagulant/antiplatelet drugs before the qualifying ICH

| | Yes | No | Unknown |
|---|--------------------------|--------------------------|--------------------------|
| Vitamin K antagonist (VKA, e.g. warfarin) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Non-VKA oral anticoagulant (NOAC) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Aspirin | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Other antiplatelet drugs, please specify: | <input type="checkbox"/> | <input type="checkbox"/> | |

7. Functional status now

| | Yes | No |
|--|--------------------------|--------------------------|
| Able to lift both arms off the bed? | <input type="checkbox"/> | <input type="checkbox"/> |
| Able to walk (with or without walking aid) without the help of another person? | <input type="checkbox"/> | <input type="checkbox"/> |
| Able to talk, and is oriented about time, place and person? | <input type="checkbox"/> | <input type="checkbox"/> |
| Modified Rankin Scale score now: <input type="text"/> | | |
| 0 No symptoms at all 1 No significant disability despite symptoms; able to carry out all usual/daily activities 2 Slight disability; unable to carry out all usual/daily activities, but able to look after own affairs without assistance 3 Moderate disability; requiring some help, but able to walk without assistance 4 Moderately severe disability; unable to walk without assistance and /attend to own bodily needs without assistance 5 Severe disability; bedridden, incontinent and requiring constant nursing care and attention | | |

8. Blood pressure at time of randomisation, and most recent serum creatinine

| | | | | |
|------------------------------------|---|-------|---|---------------------|
| Systolic/diastolic blood pressure: | <input type="text"/> / <input type="text"/> | mm Hg | <input type="text"/> / <input type="text"/> | mm Hg |
| Creatinine level: | <input type="text"/> | level | <input type="text"/> | mg/dL, or umol/L |

9. Information about the qualifying ICH

| | Yes | No | Date (ddmmyy) |
|---|--------------------------|--------------------------|--|
| What was the date of the ICH? | | | <input type="text"/> / <input type="text"/> / <input type="text"/> |
| Was only <i>supratentorial lobar</i> * region(s) affected, whether or not there was extension to ventricles and subarachnoid space? | <input type="checkbox"/> | <input type="checkbox"/> | |
| Has computed tomography (CT) been performed? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> / <input type="text"/> / <input type="text"/> |
| Has magnetic resonance imaging (MRI) been performed? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/> / <input type="text"/> / <input type="text"/> |
| *Cortical or subcortical regions of the frontal, parietal, temporal or occipital lobes | | | |

10. If this patient is randomised to a policy of “anticoagulant treatment”, which of the drugs will you prescribe?

| | Yes | No |
|-----------------------------|--------------------------|--------------------------|
| Warfarin (Marevan®, Waran®) | <input type="checkbox"/> | <input type="checkbox"/> |
| Rivaroxaban (Xarelto®) | <input type="checkbox"/> | <input type="checkbox"/> |
| Apixaban (Eliquis®) | <input type="checkbox"/> | <input type="checkbox"/> |
| Dabigatran (Pradaxa®) | <input type="checkbox"/> | <input type="checkbox"/> |
| Edoxaban (Lixiana®) | <input type="checkbox"/> | <input type="checkbox"/> |

11. If the patient is randomised to a policy of “no anticoagulant treatment”, which treatment policy will you advise/prescribe?

| | Yes | No |
|--|--------------------------|--------------------------|
| Other specific treatment for prevention of thrombosis? | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes: Antiplatelet agents? | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes: Left atrial appendage occlusion (LAAO)? | <input type="checkbox"/> | <input type="checkbox"/> |

12. Randomisation

Now enter the data on www.static.no. The computer will allocate treatment to the patient (“anticoagulant treatment”, or “no anticoagulant treatment”).

Treatment allocation: _____

13. For patients randomised to “anticoagulant treatment”: When do you plan to start?

| | Yes | No | Date (ddmmyy) |
|--|--|--------------------------|-----------------|
| Immediately/within 24 h of randomisation (preferred option) | <input type="checkbox"/> | <input type="checkbox"/> | ___ / ___ / ___ |
| Later, - when the patient returns for a routine visit | <input type="checkbox"/> | <input type="checkbox"/> | ___ / ___ / ___ |
| Later, - without the patient returning for a routine visit | <input type="checkbox"/> | <input type="checkbox"/> | ___ / ___ / ___ |
| Please add the following information on the prescription (translated from Norwegian into your language): | <ul style="list-style-type: none"> • Studiekode: EudraCT-nummer 2014-002636-13 • Til klinisk utprøving • Sponsor: Oslo universitetssykehus HF • Koordinerende utprøver: Torgeir Bruun Wyller og Ole Morten Rønning (Vakttелефон: +47 22119911) | | |