STATICH
Tel./fax.: +47 22119911/12
E-mail: k.t.larsen@medisin.uio.no
URL: www.statich.no

Patient no.: |__|__|__|__|__|

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)?	☐	☐

Inclusion criteria:
- Age ≥18 years
- Spontaneous, primary intracerebral haemorrhage (ICH), and time since onset minimum 1 day, maximum 180 days (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:
- 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		*or:* Centre no.	|__|__|__|
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	_____ /_____ /_____ dd/mm/yy		
Gender	☐ Male ☐ 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	☐	Living alone
	☐	Living with someone else
	☐	Living in an institution
	☐	Other

	Yes	No
Did the patient require assistance from anyone to undertake activities of daily living (e.g. walking, showering, toileting, dressing, feeding)?	☐	☐

4. Ischaemic vascular disease before randomisation

	Yes	No	Unknown
Ischaemic heart disease (e.g. myocardial infarction, bypass surgery, stenting)	☐	☐	☐
Peripheral arterial disease	☐	☐	☐
Symptomatic deep vein thrombosis or pulmonary embolus	☐	☐	☐
Transient ischaemic attack	☐	☐	☐
Ischaemic stroke	☐	☐	☐
Other, please specify: ……..……			
Did any of these events take place *after* the qualifying ICH?	☐	☐	☐
If yes: Please specify: ……..			

5. Other diseases/conditions before randomisation

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

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

	Yes	No	Unknown
Vitamin K antagonist (VKA, e.g. warfarin)	☐	☐	☐
Non-VKA oral anticoagulant (NOAC)	☐	☐	☐
Aspirin	☐	☐	☐
Other antiplatelet drugs, please specify: ……..…….	☐	☐	

7. Functional status now

	Yes	No
Able to lift both arms off the bed?	☐	☐
Able to walk (with or without walking aid) without the help of another person?	☐	☐
Able to talk, and is oriented about time, place and person?	☐	☐

Modified Rankin Scale score now: |__|

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:	_____ /_____	mm Hg	_____ /_____	mm Hg
Creatinine level:	_____	level	_____	mg/dL, or umol/L

9. Information about the qualifying ICH

	Yes	No	Date (ddmmyy)
What was the date of the ICH?			___ /___ /___
Was only *supratentorial lobar** region(s) affected, whether or not there was extension to ventricles and subarachnoid space?	☐	☐	
Has computed tomography (CT) been performed?	☐	☐	___ /___ /___
Has magnetic resonance imaging (MRI) been performed?	☐	☐	___ /___ /___

*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®)	☐	☐
Rivaroxaban (Xarelto®)	☐	☐
Apixaban (Eliquis®)	☐	☐
Dabigatran (Pradaxa®)	☐	☐
Edoxaban (Lixiana®)	☐	☐

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?	☐	☐
If yes: Antiplatelet agents?	☐	☐
If yes: Left atrial appendage occlusion (LAAO)?	☐	☐

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12. Randomisation

Now enter the data on www.statich.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)	☐	☐	___ /___ /___
Later, - when the patient returns for a routine visit	☐	☐	___ /___ /___
Later, - without the patient returning for a routine visit	☐	☐	___ /___ /___

Please add the following information on the prescription (translated from Norwegian into your language):	• *Studiekode: EudraCT-nummer 2014-002636-13* • *Til klinisk utprøvning* • *Sponsor: Oslo universitetssykehus HF* • *Koordinerende utprøver: Eivind Berge (Vakttelefon: +47 22119911.*