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Atrial fibrillation in stroke - Utility of Neuroimaging Evaluation

Submission date
08/05/2018

Recruitment status
No longer recruiting

Registration date
15/05/2018

Overall study status
Completed

Last Edited
21/05/2019

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients who have had a stroke are at a higher risk of having further strokes if they suffer from an abnormal rhythm of the heart (atrial fibrillation). Research suggests that beginning therapy that reduces this risk of recurrent stroke should be done within 48 hours of the stroke. However, one of the risks of this therapy is that it causes an increased risk of bleeding in the area of the brain damaged by the stroke. If this occurs, the patient has a much higher risk of poor stroke outcome and death. The purpose of this research is to improve our understanding of the timing of initiation of blood-thinning therapy in stroke patients who have an abnormal rhythm of the heart (atrial fibrillation.
To do this we are observing patients in the hospital clinical setting who begin their anticoagulant (drug that prevents blood clotting) therapy within 7 days from their stroke or after 7 days from their stroke onset. We aim to measure evidence of new "recurrent" stroke as well as any bleeding events patients may have had at 90 days after the initial stroke. We aim to compare whether it is better for patients to receive this therapy within 7 days from their stroke or after 7 days.

Who can participate?
Adults who have had a stroke related to atrial fibrillation and have been treated with anticoagulants with 1 month of their stroke.

What does the study involve?
This is an observational study, which means that participants will receive usual treatment. Participants will have an additional MRI scan at 3 months after recruitment.

What are the possible benefits and risks of participating?
We cannot guarantee or promise that participants will receive any benefits from this project. MRI imaging is a very safe assessment for most patients, as it does not use radioactive substances. However, patients with heart pacemakers and other metallic surgical implants, for example a cochlear implant, cannot be scanned. Participants will be asked a safety questionnaire before their scan to ensure it is safe to be scanned. There are no other associated risks from

participating in this study. Patients do not have to participate in this research project to receive any medical care that may be required. If patients choose not to participate they will receive the standard care that is given to patients experiencing stroke.

Where is the study run from?
Royal Melbourne Hospital

When is the study starting and how long is it expected to run for?
May 2016 to April 2022 (updated 21/05/2019, previously: February 2019)

Who is funding the study?
The Australasian Stroke Academy

Who is the main contact?
Miss Christina Lam,
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Protocol serial number
2015-11-23 NOAC registry ATTUNE_v1.4.1final

Study information

Scientific Title
A registry of clinical and MRI outcomes following early versus late initiation of anticoagulation after ischaemic stroke or transient ischaemic attack in patients with atrial fibrillation

Acronym
ATTUNE

Study objectives
1. Patients initiated on NOACs within 7 days of the stroke/TIA will have less recurrent infarction than patients initiated more than 7 days after their stroke/TIA
2. There will be no difference in haemorrhagic transformation (HT) or new intra-cerebral haemorrhage (ICH) in patients initiated on NOAC within 7 days of the stroke/TIA compared to initiation after 7 days
3. Patients initiated on NOAC within 7 days of the stroke/TIA will have fewer recurrent ischaemic events than patients initiated after 7 days
4. Early (<7 day) administration of oral anticoagulation will associate with a favorable overall cost-benefit ratio

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hunter New England Human Research Ethics Committee, 12/04/2016, 16/02/17/4.01

Study design
Prospective observational cohort study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Acute ischaemic stroke

Interventions
This is a prospective, 3-month observational cohort study using an established clinico-radiological stroke registry to examine clinical and MR imaging outcomes of patients initiated on novel oral anticoagulants (NOACs), including apixaban, rivaroxaban and dabigatran (note that edoxaban is currently unavailable in Australia) or vitamin K antagonists (VKAs), eg warfarin, within 1 month after acute stroke or transient ischaemic attack (TIA). Subjects will be analysed according to whether anticoagulant initiation was within 7 days, or after 7 days of stroke symptom onset. As this is an observational cohort study, patients undergo usual care, and the decision of when and what type of oral anticoagulant used is at the discretion of the treating

clinician.
Clinical data will include: patient demographics, pre-stroke history, previous medication history, in-hospital data (baseline and 24-hour National Institute of Health Stroke Score), reperfusion treatment, antiplatelet and anticoagulant treatment post stroke, recurrent stroke and other adverse events. Follow-up information includes clinical evidence of recurrent ischaemic stroke, TIA, intracerebral haemorrhage (ICH), and the 3-month modified Rankin scale (mRS). 3-month outcomes will be recorded centrally by phone call from the coordinating centre. This includes a scripted, validated mRS assessment.

Central Review of Imaging
All imaging will be reviewed by principal investigators of the study. Investigators will be blinded to both anticoagulation type (NOAC versus warfarin) and time frame for initiation. Imaging review will follow a proforma that assesses ischaemic change as well as ICH.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Warfarin, novel oral anticoagulants (NOACs) including apixaban, rivaroxaban and dabigatran

Primary outcome(s)
New ischaemic lesions on MRI at 1 month

Key secondary outcome(s))
1. New clinical stroke within 90 days determined by clinic review or telephone follow up
2. Intracerebral haemorrhage on MRI at 1 month
3. Disability or dependence following stroke, assessed by mRS at 90 days determined by clinic review or telephone follow up
4. Non-intracranial bleeding within 90 days

Completion date
01/04/2022

Eligibility

Key inclusion criteria
1. Patients who present with an acute ischaemic stroke or TIA of cardioembolic (atrial fibrillation [AF]-related) origin and who have an MRI following their primary ischaemic event, and are deemed suitable for initiation of NOAC or VKA therapy
2. Subjects must be enrolled within 30 days of symptom onset

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Evidence of primary intracranial haemorrhage
2. Inability to have baseline and follow-up MRI

Date of first enrolment
21/05/2016

Date of final enrolment
01/01/2022

Locations

Countries of recruitment
Australia

Study participating centre
Royal Melbourne Hospital
300 Grattan Street Parkville
Melbourne
Australia
3050

Study participating centre
John Hunter Hospital
Australia
2305

Study participating centre
Flinders Medical Centre
Australia
5042

Study participating centre
Royal North Shore hospital
Australia
2065

Study participating centre
Royal Prince Alfred Hospital
Australia
2050

Study participating centre
Westmead Hospital
Australia
2145

Study participating centre
Gold Coast University Hospital
Australia
4215

Study participating centre
Princess Alexandra Hospital
Australia
4102

Study participating centre
Royal Brisbane Hospital
Australia
4029

Study participating centre
Calvary Wakefield Hospital
Australia
5000

Study participating centre
Royal Adelaide Hospital
Australia
5000

Study participating centre
The Alfred Hospital
Australia
3004

Study participating centre
Austin Hospital
Australia
3084

Study participating centre
Monash Medical Centre Clayon
Australia
3168

Study participating centre
The Northern Hospital
Australia
3076

Study participating centre
University Hospital Geelong
Australia
3220

Study participating centre
Western Hospital
Australia
3021

Study participating centre
Calvary Public Hospital Bruce
Australia
2617

Study participating centre

Epworth Eastern
Australia
3128

Sponsor information

Organisation
Australasian Stroke Academy

Funder(s)

Funder type
Not defined

Funder Name
Andrew Lee - Chief Executive Officer of the Australasian Stroke Academy

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Stored in repository