ISRCTN15698516 https://doi.org/10.1186/ISRCTN15698516

Stroke: an evaluation of thrombectomy in the ageing brain version 1 (STABILISE)

Submission date
08/01/2015

Recruitment status
No longer recruiting

Registration date
09/01/2015

Overall study status
Completed

Last Edited
26/02/2018

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
Stroke is a serious, life-threatening medical condition that usually happens when a blood clot or haemorrhage cuts of the blood supply to an area of the brain. Symptoms vary according to how much of the brain is affected and where in the brain the stroke occurs, but includes paralysis, muscle weakness and speech difficulties. They can often be treated with a “clotbusting” (“thrombolytic”) drug. However, a “clotbusting” drug is less likely to open the blocked blood vessel if the clot is larger and some people have medical conditions that mean it is not safe to give them a clot busting drug. Medical devices that can remove clots (clot pullers or retrievers) may be used as an additional treatment to thrombolysis or instead of no active treatment where thrombolysis cannot safely be given. The procedure is called thrombectomy. Such devices are more likely to open up the blocked blood vessel, but are more complicated to use. This study investigates whether treatment using a purpose designed new clot retrieval device is at least as safe and effective in unblocking the occluded blood vessel after an acute stroke as existing devices. The new device has design features that may be particularly useful in elderly patients. This study investigates whether additional brain imaging would be helpful in acute stroke patients treated with clot pullers by:
1. Examining whether analysis of blood vessels on the scans taken before treatment starts can predict who will or will not do well, and see if there is any link to age.
2. Detailed MRI brain scan 24h after treatment to see if scan findings at that stage can predict long term outcome, identify complications not appreciated on routine CT and see whether these are linked to patient age.

Who can participate?
Adults aged at least 50 diagnosed with a stroke caused by a blocked artery (acute ischaemic stroke).

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 have a thrombectomy performed using the new device. Those in group 2 have a thrombectomy performed using the standard device. The safety and efficacy of the novel thrombectomy device is assessed after the procedure. All participants have an MRI brain scan 24 hours after treatment.

What are the possible benefits and risks of participating?
The study population has a high risk of adverse events as a direct consequence of the condition being treated. All patients undergo standard best medical therapy for them, including where indicated, IV thrombolysis as well as thrombectomy and none of the risks/discomfort /inconvenience possible from these are related to participation in the study. The main inconvenience/intrusion comes from approaching the patient, or more likely a relative, about participation in a research study at a time of natural concern and anxiety following major stroke. However, all teams involved in the study will be accustomed to recruiting patients into hyperacute research studies, including one involving thrombectomy (PISTE or similar) and will have appropriate experience and training for this role. Patient/Consultee information sheets including a short summary sheet and an introductory 1-page information sheet will be available to assist a sensitive, informed approach.

Where is the study run from?
Newcastle Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
November 2014 to April 2019

Who is funding the study?
Biomedical Research Centre (UK)

Who is the main contact?
Miranda Morton

Contact information

Type(s)
Scientific

Contact name
Ms Miranda Morton

Contact details
Newcastle Clinical Trials Unit
Faculty of Medical Sciences
Newcastle University
1-4 Claremont Terrace
Newcastle upon Tyne
United Kingdom
NE2 4AE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

17942

Study information

Scientific Title
Stroke: an evaluation of Thrombectomy in the Ageing Brain [including] where IV thromboLysis is contraindicated

Acronym
STABILISE

Study objectives
This study will investigate whether treatment using a purpose designed new clot retrieval device is at least as safe and effective in unblocking the occluded blood vessel after an acute ischaemic stroke as existing devices. The new device has design features that may be particularly useful in elderly patients with more difficult vascular access.
This study will investigate whether additional brain imaging would be helpful in acute stroke patients treated with clot retrieval by:
1. Examining whether analysis of blood vessels on the scans taken before treatment starts can predict who will or will not do well, and see if there is any link to age.
2. Detailed MRI brain scan 24h after treatment to see if scan findings at that stage can predict long term outcome, identify complications not appreciated on routine CT and see whether these are linked to patient age.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East – Newcastle & North Tyneside, 04/07/2014, ref: 14/NE/0113

Study design
Randomised; Interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Stroke; Subtopic: Acute Care; Disease: Device used

Interventions
Thrombectomy performed via randomisation with standard or new device.

Intervention Type
Procedure/Surgery

Primary outcome measure
Safety and efficacy of novel thrombectomy device, based on the angiographic run at the end of the procedure

Secondary outcome measures
1. Safety – intracranial haemorrhage at 24 hours, others will be throughout the follow up period
2. Feasibility – at day 1, 90 and 180
3. Neurological recovery – mRS at day 90 and 365
4. Early major neurological improvement – at 72 hours
5. Sustained recanalization – 24h
6. Days spent at home – 90 days
7. Mortality – 365 days
8. Collateral score on CTA & clinical outcome – 365 days
9. MRI marker of procedural risk – 24 hours

Overall study start date
01/11/2014

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. Clinical diagnosis of acute ischaemic stroke
2. Male or nonpregnant female at least 50 years of age
3. Clinically significant neurological deficit and NIHSS score 10 or greater
4. Enrolment, randomisation and procedure commencement (groin puncture) possible within 90 minutes of theimaging (CT/CTA) confirmed diagnosis of LVO (AND maximum 5h after stroke onset anterior circulation, 8.5h for posterior circulation).
5. Occlusion of the MCA trunk, MCA bifurcation or intracranial internal carotid artery (including carotidT),M1 or =2 proximal M2 branches; intracranial vertebral/basilar/P1 PCA demonstrated on CTA, MRA, or DSA
6. Interventional device delivery (guide catheter placed in target artery beyond aortic arch and angio obtained) can be achieved within 6 hours of onset of the stroke (9h for posterior circulation occlusions)
7. Consent of patient or assent of appropriate representative
8. Independent prior to the stroke (estimated mRS 02)
9. Expected to be able to be followed up at 12 months

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria
1. CT evidence of ICH, or evidence of extensive established hypodensity on CT(defined as >1/3 MCA territory orASPECTS score =7). In posterior circulation strokes pcASPECTS <7 or >1/3 of territory
2. Clinical history suggestive of subarachnoid haemorrhage even if CT normal.
3. Eligible for an academic “treatment policy” (i.e. phase III trial) RCT of stroke thrombectomy in that institution & willing to be randomised into such
4. Vascular access contraindications e.g. bilateral femoral bypass surgery, tight ipsilateral carotid or vertebral stenosis (if judged not readily amenable to acute intervention by Interventional Neuroradiologist [INR] who would carry out the
procedure), unsuitable proximal vascular anatomy likely to render endovascular catheterisation difficult, unsafe or impossible (as judged by INR who would carry out the procedure)
5. Extracranial: chronic/atherosclerotic ipsilateral ICA or dominant vertebral artery occlusion
6. Alternative intracranial pathology potentially responsible for the new symptoms
7. Medical comorbidities which would preclude safe cerebral vessel catheterisation or which are expected to limit life expectancy to <3 months (eg severe cardiac, renal or hepatic failure, significant coagulopathy, metastatic malignancy)
8. Known allergy to radiological contrast
9. Absolute contraindication to MRI

Date of first enrolment
01/11/2014

Date of final enrolment
31/01/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle Clinical Trials Unit
Faculty of Medical Sciences
Newcastle University
1-4 Claremont Terrace
Newcastle upon Tyne
United Kingdom
NE2 4AE

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Biomedical Research Centre (UK)

Results and Publications

Publication and dissemination plan

Intention to publish date

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
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No