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Vertebral artery stenting trial

Submission date
14/02/2008

Recruitment status
No longer recruiting

Registration date
20/03/2008

Overall study status
Completed

Last Edited
18/03/2016

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
About 85% of strokes are ischemic strokes. Ischemic strokes happen when the arteries that supply the brain with oxygen become narrowed (stenosed) or blocked (occluded), causing severely reduced blood flow (ischemia). As we age, a gradual build-up of a sticky substance called plaque can occur in our arteries. When there is a lot of plaque, particularly with a rough or irregular surface, blood clots can develop, depriving the brain of oxygen and leading to an acute ischemic stroke (AIS). This can also be the cause of a transient ischaemic attack (TIA), often referred to as a mini-stroke as it does not last long and rarely causes complications. The vertebral arteries are major arteries in the neck which, along with the carotid arteries, control the blood supply to the brain. Stenosis and occlusion of the vertebral arteries is less common than in the carotid arteries, however around 30% of ischaemic strokes are thought to arise from stenosis of the vertebral artery. The risk of someone with vertebral artery stenosis having a stroke is not really known and surgery to widen the artery (angioplasty) is rarely performed, although it could potentially reduce the risk of stroke. The aim of this study is to find out whether surgically reopening stenosed vertebral arteries is a feasible and safe procedure, and whether it could help reduce the risk of further vascular events (death from all vascular causes, non-fatal stroke, or non-fatal heart attack).

Who can participate?
Adults aged 40 or over who have had a TIA or non-disabling ischaemic stroke who have a reduction of at least 50% in the diameter of their vertebral artery (stenosis).

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo an angioplasty procedure on their vertebral artery, followed by stenting (if appropriate). This involves a small balloon being inflated in the artery in order to flatten the blockage against the artery wall to increase its diameter. A mesh tube is then put in place to hold the artery open. Those in the second group are treated at the discretion of their doctor, using medications to prevent blood clots (blood thinners). After 30 days, the amount of patients in each group who have had a vascular event are recorded.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
UMC Utrecht (Netherlands)

When is the study starting and how long is it expected to run for?
April 2008 to December 2012

Who is funding the study?
Netherlands Heart Foundation (Netherlands)

Who is the main contact?
Dr H. Bart van der Worp
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
Stenting of symptomatic vertebral artery stenosis: a randomised safety and feasibility study

Acronym
VAST

Study objectives
1. In patients with symptomatic vertebral artery stenosis of 50% or greater, stenting of the stenosis is both feasible and safe
2. In the present trial, sufficient information will be obtained about whether and how a conclusive clinical trial should be developed in which endovascular treatment plus best medical treatment will be compared to best medical treatment alone in patients with symptomatic vertebral artery stenosis of at least 50%

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Review Board of the University Medical Centre in Utrecht (The Netherlands), 22/01/2008, ref: 07-245/E

Study design
Randomised open multicentre clinical trial with masked outcome assessment

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 the contact details below to request a patient information sheet. Patient information is available in Dutch.

Health condition(s) or problem(s) studied
Symptomatic stenosis of a vertebral artery of at least 50%

Interventions
The trial will compare the combination of vertebral artery stenting and best medical treatment with best medical treatment alone. The type of stent and the use of a protection device will be left to the discretion of the interventionist. If stent placement is not feasible or deemed contra-indicated, angioplasty without stent placement will be performed. All patients randomised to stenting will receive clopidogrel 75 mg daily starting at least five days before the procedure and continued for 30 days after the procedure. Patients not on clopidogrel the day before the procedure will be loaded with 300 mg clopidogrel at least six hours before stenting. Best medical treatment will be left to the discretion of the neurologist, but should include rigorous control of vascular risk factors, the use of antiplatelet agents, and the use of a statin.

Follow-up will continue until one year after inclusion of the last patient, which is expected in December 2011. 'Best medical treatment' will be continued for the entire duration of the trial (and thereafter).

Intervention Type
Mixed

Primary outcome measure
Vascular death, non-fatal myocardial infarction, or non-fatal stroke (neurological deficit lasting longer than 24 hours for which no other cause than a stroke can be found) within 30 days after start of the treatment.

Secondary outcome measures
1. Vascular death, non-fatal myocardial infarction, or non-fatal stroke during follow-up*
2. Any stroke in the supply territory of the symptomatic vertebral artery during follow-up*
3. Degree of stenosis of the symptomatic vertebral artery after one year, as assessed with both Duplex ultrasound and CT angiography

*Follow-up visits will be performed at one day and at 1, 6, and 12 months after stenting (or randomisation in the conservative treatment group) and every year thereafter. The close-out visit of each patient will be scheduled one year after randomisation of the last patient, expected in December 2011.

Overall study start date
01/04/2008

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Transient ischaemic attack (TIA) or non-disabling ischaemic stroke of the posterior circulation
2. Symptoms must have occurred in the 180 days preceding randomisation
3. Possibility to perform stenting within two weeks after randomisation
4. Stenosis of the vertebral artery of 50% or greater, diagnosed by both duplex ultrasound and computed tomography (CT-), contrast-enhanced magnetic resonance (MR-), or conventional angiography, and presumed to be of atherosclerotic origin and accessible for endovascular treatment
5. Score on the modified Rankin scale less than or equal to 3 (independent in daily activities, although some help may be needed)
6. Aged 40 years or older, either sex
7. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
180

Key exclusion criteria
1. Potential cause of TIA or minor stroke other than stenosis in a vertebral artery (e.g. atrial fibrillation)
2. Vertebral artery stenosis caused by arterial dissection
3. Previous surgical or endovascular treatment of the stenosis
4. Life expectancy shorter than three years
5. Other serious illness that may confound outcome assessment

Date of first enrolment
01/04/2008

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
UMC Utrecht
Utrecht
Netherlands
3584 CX

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

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Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Heart Foundation (Nederlandse Hartstichting) (NHS) (The Netherlands) (ref: 2007B045)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2015		Yes	No