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A trial of cerebral angioplasty for post-subarachnoid haemorrhage symptomatic vasospasm

Submission date 29/06/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/11/2006	**Overall study status** Completed	
Last Edited 10/08/2017	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A trial of cerebral angioplasty for post-subarachnoid haemorrhage symptomatic vasospasm: an interventional randomised controlled trial

Acronym
VERITAS

Study objectives
We aim to examine the hypothesis that cerebral balloon angioplasty (CBA) and best medical treatment compared with best medical treatment alone will substantially reduce the proportion of patients with an unfavourable outcome following the development of symptomatic cerebral vasospasm with associated delayed ischaemic neurological deficit (DIND) after aneurysmal subarachnoid haemorrhage (ASAH).

On 04/03/2009 the overall trial end date was changed from 01/12/2010 to 01/06/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scottish MREC and MREC gave approval

Study design
Interventional randomised controlled trial with concealed allocation and minimisation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Symptomatic vasospasm post-aneurysmal subarachnoid haemorrhage

Interventions
Cerebral balloon angioplasty and standard medical therapy versus standard medical therapy alone

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Death/disability at three months as assessed by Modified Rankin Score (MRS) and National Institute of Health Stroke Scale (NIHSS) determined by independent 'blinded' neurologist

Secondary outcome measures
1. Clinical outcome at one year (MRS & Euroquol instrument assessment)
2. Duration of stay in Intensive Care Unit (ICU)/hospital
3. Discharge destination
4. Requirement for extended care facilities
5. Cost assessment of CBA versus control group

Overall study start date
01/12/2006

Completion date
01/06/2012

Eligibility

Key inclusion criteria
1. Have a documented SAH from a ruptured aneurysm
2. Ruptured aneurysm must be secured by coiling or clipping
3. Patients have developed a delayed ischaemic neurological deficit, this is defined as any one of:
3.1. Clear focal neurological deficit developing after 72 hours post ictus
3.2. Falling Glasgow Coma Score (GCS) by two or more points after 72 hours post ictus
3.3. Increasingly severe headache after 72 hours post ictus with confirmation of angiographic vasospasm
For points a + b clinical suspicion of symptomatic vasospasm should be confirmed where possible by imaging demonstration of vasospasm (this can be by any standard technique: Angiography, Trans-Cranial Doppler sonography (TCD), Single Photon Emission Computerised Tomography (SPECT), CT or Magnetic Resonance (MR) angio/perfusion)
4. Informed consent/assent in line with local and multicentre ethics approval
5. Rebleeding and hydrocephalus have been excluded on Computerised Tomography (CT) brain scan
6. Availability of CBA within 24 hours of DIND symptom onset (aim is to perform CBA as soon as possible after onset of symptomatic vasospasm - timing related to symptom onset will be recorded)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Consent unobtainable from patient (World Federation of Neurosurgical Sciences [WFNS] grade four or five, or grade three but dysphasic) or no personal or professional legal representative available to assent on their behalf
2. Another cause for deterioration/ischaemic deficit demonstrated
3. Participation in another clinical neurointerventional trial related to the management of ASAH
4. Pregnancy is also an exclusion criterion

Date of first enrolment
01/12/2006

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Western General Hospital
Edinburgh
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Sponsor information

Organisation
Lothian University Hospitals Division (UK)

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Sponsor type
University/education

Website
http://www.research.luht.scot.nhs.uk/

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Charity

Funder Name
Chest, Heart & Stroke Scotland (UK) - funding for start up phase supplied

Funder Name
Other funders still being sought.

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