

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

Submission date 29/06/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/11/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/08/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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 sub-arachnoid 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Scotland

Study participating centre

Western General Hospital

Edinburgh

United Kingdom

EH4 2XU

Sponsor information

Organisation

Lothian University Hospitals Division (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration