# A trial of cerebral angioplasty for postsubarachnoid haemorrhage symptomatic vasospasm

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

#### Contact name

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# Additional identifiers

**Protocol serial number** 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

### 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

EH4 2XU

Study participating centre Western General Hospital Edinburgh United Kingdom

# 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