

# Hydrocoil: Endovascular Aneurysm Occlusion and Packing Study

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|--|---|---|
| <b>Submission date</b><br>31/07/2004   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>01/04/2005 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>14/11/2013       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data  |

**Plain English summary of protocol**  
Not provided at time of registration

**Study website**  
<http://www.helpstudy.org/>

## 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

### Acronym

HELPS

### Study objectives

The HELPS (hydrocoil: endovascular aneurysm occlusion and packing study) trial aims to compare major aneurysm recurrence rate on follow-up angiography at 15 - 18 months between patients allocated hydrocoil versus patients allocated bare platinum coiling.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration.

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Patient information sheet can be found at <http://www.mymainplace.com/HelpStudy/Collateral/PIS%20V3.doc>.

### Health condition(s) or problem(s) studied

Intracranial aneurysms

### Interventions

This study is now closed to recruitment.

Patients are randomised to the hydrogel coil or control arms by using concealed allocation with minimisation matching groups. Any bare platinum coils are allowed in the control arm, and assist devices could be used as clinically required.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Angiographic outcomes at 15-18 months between aneurysms coiled using bare platinum coils (control group) and those coiled using hydrocoil embolic system.

**Secondary outcome measures**

Secondary outcome measures include packing density, clinical outcome, rebleed and retreatment comparisons between these 2 groups.

**Overall study start date**

01/09/2004

**Completion date**

30/06/2008

**Eligibility****Key inclusion criteria**

Patient presenting with a cerebral aneurysm deemed to require endovascular treatment by the neurosurgeon/neurointerventionist (generically referred to subsequently as 'the neurovascular team'), and:

1. Patient has given fully informed consent to endovascular coiling procedure
2. Aneurysm 2 - 25 mm in maximum diameter
3. Anatomy such that endovascular occlusion is deemed possible (not necessarily probable)
4. The neurointerventionist is content to use either bare platinum or hydrocoil embolic system (HES) depending on randomisation result (i.e., clinical equipoise principle applies)
5. The neurointerventionist is content not to use any other type of coated coil
6. Patient World Federation of Neurological Surgeons (WFNS) Grade 0 - 2 and aged 18 - 75 years
7. The patient has not been previously randomised into this trial
8. Aneurysm has not previously been treated (by coiling or clipping)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

500

**Key exclusion criteria**

Subjects will not be considered for the trial unless they meet all the inclusion criteria. If the patient has more than one aneurysm requiring treatment at the same treatment episode they will not be eligible for the trial. If treatment will be staged in a patient with multiple aneurysms and only one aneurysm will be treated at one sitting then the patient is eligible. However, a patient may not be randomised into the study more than once.

From the moment of randomisation, the patient is in the trial whether they receive trial treatment or not, and will be followed up and accounted for in the final analysis (intention-to-treat).

Death or procedural/disease related morbidity may result in some subjects not having check angiography (or magnetic resonance angiography [MRA] if unit uses this as standard mode of follow-up). These patients will be counted as poor outcomes in the primary analysis.

Retreatment of previously coiled or clipped aneurysm is an exclusion criteria.

Use of coil assist devices (stent, balloon, trispan etc.) should be recorded but is not an exclusion criteria. It must be recorded in order to ascertain if any difference in use between control and hydrocoil groups acts as a potential confounding variable.

**Date of first enrolment**

01/09/2004

**Date of final enrolment**

30/06/2008

**Locations****Countries of recruitment**

Argentina

Australia

Brazil

France

Germany

Scotland

United Kingdom

United States of America

**Study participating centre**

**Dept. of Neuroradiology**

Edinburgh

United Kingdom  
EH4 2XU

## Sponsor information

### Organisation

Lothian University Hospitals Division (UK)

### Sponsor details

Research & Development Office, Room G8137  
Royal Infirmary of Edinburgh  
Little France Crescent  
Edinburgh  
Scotland  
United Kingdom  
EH16 4SA  
neil.feltham@luht.scot.nhs.uk

### Sponsor type

Hospital/treatment centre

### Website

<http://www.research.luht.scot.nhs.uk/>

### ROR

<https://ror.org/03q82t418>

## Funder(s)

### Funder type

Industry

### Funder Name

Microvention Incorporated (USA)

### Funder Name

Lothian University Hospitals Division (UK)

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/02/2008   |            | Yes            | No              |
| <a href="#">Results article</a> | results | 14/05/2011   |            | Yes            | No              |