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# Hydrocoil: Endovascular Aneurysm Occlusion and Packing Study

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 31/07/2004 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 01/04/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 14/11/2013 | Circulatory System | |

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

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Philip White

**Contact details**
Dept. of Neuroradiology
Western General Hospital
Crewe Road
Edinburgh
United Kingdom
EH4 2XU
pmw@skull.dcn.ed.ac.uk

## Additional identifiers

## 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.

### Primary study design
Interventional

### Study design
Randomised controlled trial

### Study type(s)
Treatment

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

### Key secondary outcome(s)
Secondary outcome measures include packing density, clinical outcome, rebleed and retreatment comparisons between these 2 groups.

### 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

## Healthy volunteers allowed
No

## Age group
Adult

## Lower age limit
18 Years

## Sex
All

## 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**
United Kingdom

Scotland

Argentina

Australia

Brazil

France

Germany

United States of America

**Study participating centre**
**Dept. of Neuroradiology**
Edinburgh
United Kingdom
EH4 2XU

# Sponsor information

**Organisation**
Lothian University Hospitals Division (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

## 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 | 01/02/2008 | | Yes | No |
| Results article | results | 14/05/2011 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |