ISRCTN30531382 https://doi.org/10.1186/ISRCTN30531382

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.

Study design
Randomised controlled trial

Primary study design
Interventional

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