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Treatment of Intracranial Aneurysms using vascular Reconstruction Assist device

Submission date 02/02/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/04/2011	**Overall study status** Completed	
Last Edited 05/04/2016	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
An intracranial aneurysm is a bulge in a blood vessel in the brain, caused by a weakness in the vessel wall. If it bursts (ruptures) this leads to bleeding and brain damage. Preventative surgery is recommended if there is a high risk of a rupture. Endovascular coiling involves inserting a thin tube into the aneurysm and passing tiny metal coils into the aneurysm to seal it off, preventing it from growing or rupturing. The aim of this study is to find out whether inserting a self-expanding tube (stent) into the aneurysm to assist coiling improves the outcome for the patient.

Who can participate?
Patients aged 18-70 with an intracranial aneurysm

What does the study involve?
Participants are randomly allocated to be treated with coiling either with or without stent assistance. Participants are assessed by angiography (a type of x-ray used to examine blood vessels) 12 months later to check for aneurysm recurrence.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Western General Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2011 to June 2016

Who is funding the study?
Microvention Terumo Inc. (USA)

Who is the main contact?
Dr Philip White
pmw@skull.dcn.ed.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Philip White

Contact details
DCN X-Ray
Western General Hospital
Crewe Road
Edinburgh
United Kingdom
EH4 2XU
-
pmw@skull.dcn.ed.ac.uk

Additional identifiers

Protocol serial number
Version 3/08/2010

Study information

Scientific Title
Treatment of Intracranial Aneurysms using a vascular Reconstruction Assist device: a randomised controlled trial of self expanding stent (conventional mesh density) plus coiling versus coiling +/- temporary assist techniques

Acronym
TIARA

Study objectives
Use of self-expanding stent will not improve angiographic outcome at 12 months (as assessed by independent core laboratory)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending from UK Integrated Research Application System (IRAS). All other centres will seek ethics approval before recruitment of the first participant.

Study design
Prospective multinational randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cerebrovascular - aneurysms

Interventions
Aneurysm coiling +/- stent assistance

Intervention Type
Procedure/Surgery

Primary outcome(s)
Major angiographic recurrence rate at 12 months post procedure

Key secondary outcome(s))
1. Procedural outcomes (procedural morbidity & mortality)
2. Clinical outcomes: Modified Rankin Scale (MRS) at discharge, 90 days and 1 year
3. Re-bleed & retreatment rates at 1 year (and to end of trial follow-up)
4. Non target aneurysm bleeding events resulting in hospitalisation or other serious adverse event (AE) within 30/7 of target procedure resulting in hospitalisation

Completion date
01/06/2016

Eligibility

Key inclusion criteria
1. Age range 18-70 (evidence that procedural risk for stent placement in over 70 is 4 fold greater and saccular aneurysms are extremely uncommon under 18)
2. Patient world federation of neurosurgeons (WFNS) Grade 0-2 [anticipated most patients recruited will be 0]
3. Aneurysm judged suitable for treatment by coiling plus or minus the stent assistance and operator content to use/not use stent according to randomisation treatment allocation result
4. Aneurysm greater than or equal to 8mm in maximal diameter, with aneurysm neck greater than 4mm or dome to neck ratio less than 2:1, but less than 25mm in size. If target aneurysm previously treated by coiling the recurrence must have a maximal diameter in this range
5. If a patient presents with subarachnoid haemorrhage (SAH) and staged treatment with delayed stenting is judged appropriate due to aneurysm size/neck width then the patient is eligible

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
1. Does not meet aneurysm size/neck characteristics outlined in inclusion criteria
2. Less than18 years or more than 70 years of age
3. Pregnant
4. Unable to consent for themselves
5. Non-saccular aneurysm - e.g. blister, fusiform or definitely dissecting aneurysm
6. Subarachnoid hemorrhage (SAH)/intracerebral haemorrhage from another aneurysm or intracranial lesion within last 28 days
7. Major surgery within last 30 days (or any other medical situation where dual antiplatelet therapy is contraindicated in the opinion of the responsible neurovascular team)
8. Intention to deploy flow diverting device/construct as primary aneurysm treatment
9. More than one aneurysm requiring treatment in current procedure
10. Target or a nearby aneurysm has had previous stent treatment such that a Vascular Reconstruction Device [VRD i.e. a stent] is already across all or greater than 1/3 of the neck of the target aneurysm
11. Medical or surgical co-morbidity such that the patients life expectancy is less than 1 year
12. The patient has been previously randomised into this trial
13. Patient has been randomised into another trial of an endovascular device for aneurysm treatment within the last 6 months
14. Deployment of stent judged essential to treat the aneurysm

Date of first enrolment
01/06/2011

Date of final enrolment
01/06/2016

Locations

Countries of recruitment
United Kingdom

Scotland

Germany

Korea, South

Netherlands

Sweden

United States of America

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
Industry

Funder Name
Microvention Terumo Inc. (United States of America)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration