

Treatment of Intracranial Aneurysms using vascular Reconstruction Assist device

Submission date 02/02/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/04/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

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Contact information

Type(s)

Scientific

Contact name

Dr Philip White

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cerebrovascular - aneurysms

Interventions

Aneurysm coiling +/- stent assistance

Intervention Type

Procedure/Surgery

Primary outcome measure

Major angiographic recurrence rate at 12 months post procedure

Secondary outcome measures

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

Overall study start date

01/06/2011

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

550

Key exclusion criteria

1. Does not meet aneurysm size/neck characteristics outlined in inclusion criteria

2. Less than 18 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**

Germany

Korea, South

Netherlands

Scotland

Sweden

United Kingdom

United States of America

Study participating centre

Western General Hospital

Edinburgh

United Kingdom

EH4 2XU

Sponsor information**Organisation**

Lothian University Hospitals Division (UK)

Sponsor details

NHS Lothian

Research and Development Office

Queen Medical Research Institute

47 Little France Crescent

Edinburgh

United Kingdom

EH16 4TJ

Sponsor type

Government

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Microvention Terumo Inc. (United States of America)

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