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Trial on Endovascular Management of Unruptured Aneurysms

Submission date 11/09/2006	**Recruitment status** Stopped	[_] Prospectively registered [X] Protocol
Registration date 12/09/2006	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 10/02/2021	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
A brain (intracranial) aneurysm is a bulging, weak area in the wall of a blood vessel supplying blood to the brain. Most aneurysms only cause symptoms if they burst (rupture), which leads to bleeding (haemorrhage) and brain damage. Surgery is recommended if there's a high risk of rupture. Endovascular coiling involves inserting a thin tube into a blood vessel in the leg or groin, which is guided through the blood vessels and into the aneurysm, where tiny coils are passed through the tube into the aneurysm, sealing it off and preventing it from rupturing. The aim of this study is to assess the safety and effectiveness of endovascular treatment at preventing aneurysmal haemorrhage.

Who can participate?
Patients aged 18 or over with an unruptured aneurysm

What does the study involve?
Participants are randomly allocated to one of two groups. One group is treated with endovascular coiling and the other group receives conservative management (watchful observation). Participants are followed up after 1, 5 and 10 years.

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

Where is the study run from?
Centre Hosp. de l'Université de Montréal (CHUM) (Canada)

When is the study starting and how long is it expected to run for?
August 2006 to September 2023

Who is funding the study?
1. Canadian Institutes of Health Research (CIHR) (Canada)
2. NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Contact information

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00537134

Protocol serial number
HTA 06/404/50; MCT-80799

Study information

Scientific Title
Safety and efficacy of endovascular treatment of unruptured intracranial aneurysms in the prevention of aneurysmal haemorrage: a randomised comparison with indefinite deferral of treatment

Acronym
TEAM

Study objectives
The ten year combined mortality and morbidity (M/M) related to unruptured aneurysms observed in the conservative group will decrease from 8% to 4% (M/M of treatment and haemorrhagic events despite treatment as expressed by a modified Rankin scale more than or equal to three) with endovascular treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Comité d'éthique de la recherche Équipe Hôpital Notre-Dame du CHUM, 15/06/2006
2. Ethics approvals for centers in other countries are pending

Study design
Multicentre multicountry randomised two-arm parallel trial with study investigator and outcomes assessor blinded

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intracranial aneurysm

Interventions
Intervention group: Endovascular coiling of aneurysm, upon diagnosis
Control group: Conservative management/observation, upon diagnosis

Intervention Type
Procedure/Surgery

Primary outcome(s)
Disease or treatment-related morbidity and mortality, measured at one year, five and ten years after treatment or observation.

Key secondary outcome(s))
1. To better define the natural history of unruptured aneurysms eligible for endovascular treatment, measured at five and ten years

2. Define the rate of haemorrhagic events despite endovascular treatment at one year, five and ten years
3. Determine the M/M related to endovascular treatment of unruptured aneurysms at one year, five and ten years
4. Compare overall M/M of the two groups at ten years
5. Compare the quality of life and anxiety levels of surviving patients of the two groups at five and ten years
6. Determine the rate of occlusion of aneurysms treated by coiling in an effort to estimate longer-term efficacy at five and ten years
7. Determine the rate of aneurysmal growth in the conservative group in surviving patients at five and ten years
8. Verify cognitive functions using the Montreal Cognitive Assessment (MoCA) in all patients at baseline, one year, five and ten years; as well as by detailed neuropsychological testing at baseline and six months after treatment in a consecutive sample of 100 patients of both groups

Completion date
30/09/2023

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. At least one documented subarachnoid aneurysm between 3 and 25 mm, never ruptured
2. Patient aged 18 or older, either sex
3. Life expectancy more than ten years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with intracranial haemorrhage
2. Lesion characteristics unsuitable for endovascular treatment
3. Patients with single cavernous aneurysms
4. Aneurysms less than 3 mm or giant aneurysms (more than or equal to 25 mm)
5. Patients with a poor outcome (Rankin scale more than or equal to three) after the rupture, surgical or endovascular treatment of another aneurysm

6. Patients with incompletely treated aneurysms that have previously ruptured
7. Patients with associated arteriovenous malformations
8. Patients with new severe progressive symptoms in relationship with the aneurysm (sudden onset, severe persisting headaches suggestive of impending rupture, third-nerve palsy, mass-effect)
9. Patients with previous intracranial haemorrhage from unknown aetiology
10. Patients with multiple unruptured aneurysms in whom surgical clipping of one or many aneurysms is planned in addition to endovascular management
11. Patients with absolute contraindications to anaesthesia, endovascular treatment, or administration of contrast material, including low-osmolarity agents or gadolinium
12. Pregnant patients

Date of first enrolment
01/08/2006

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
United Kingdom

Australia

Canada

Chile

China

Czech Republic

France

Germany

Greece

Italy

Norway

Russian Federation

Spain

Switzerland

Türkiye

United States of America

Study participating centre
Centre de Recherche du CHUM - Notre-Dame
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Sponsor information

Organisation
Centre Hosp. de l'Université de Montréal (CHUM) (Canada)

ROR
https://ror.org/0410a8y51

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-80799)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name

Health Technology Assessment Programme: UK trial sites will be funded by the HTA programme from 01/06/2008 for five years

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2007		Yes	No
Protocol article	protocol	01/01/2008		Yes	No
Protocol article	protocol	16/07/2008		Yes	No