

# Trial on Endovascular Management of Unruptured Aneurysms

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<b>Registration date</b> 12/09/2006	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/02/2021	<b>Condition category</b> 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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00537134

## Secondary identifying numbers

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 haemorrhage: 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

## 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

Intracranial aneurysm

## **Interventions**

Intervention group: Endovascular coiling of aneurysm, upon diagnosis

Control group: Conservative management/observation, upon diagnosis

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

Disease or treatment-related morbidity and mortality, measured at one year, five and ten years after treatment or observation.

## **Secondary outcome measures**

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

## **Overall study start date**

01/08/2006

## **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

## **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

2000

**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-osmolality agents or gadolinium
12. Pregnant patients

**Date of first enrolment**

01/08/2006

**Date of final enrolment**

30/09/2023

**Locations****Countries of recruitment**

Australia

Canada

Chile

China

Czech Republic

France

Germany

Greece

Italy

Norway

Russian Federation

Spain

Switzerland

Türkiye

United Kingdom

United States of America

**Study participating centre**

**Centre de Recherche du CHUM - Notre-Dame**

Quebec

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## **Sponsor information**

**Organisation**

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

**Sponsor details**

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**Sponsor type**

University/education

**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, Canadian Institutes of Health Research (CIHR), CIHR\_IRSC, Canadian Institutes of Health Research | Ottawa ON, 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, HTA

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	01/03/2007		Yes	No
<a href="#">Protocol article</a>	protocol	01/01/2008		Yes	No
<a href="#">Protocol article</a>	protocol	16/07/2008		Yes	No