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Asymptomatic Carotid Surgery Trial 2: an international randomised trial to compare carotid endarterectomy with carotid artery stenting to prevent stroke

Submission date
11/05/2006

Recruitment status
No longer recruiting

Registration date
03/07/2006

Overall study status
Ongoing

Last Edited
04/04/2025

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Stroke causes about 10% of all deaths worldwide, and much serious disability. Many strokes are caused by thick fatty deposits narrowing the carotid arteries, which are the main blood vessels in the neck that supply blood to the brain. People with this condition, called carotid artery stenosis, may have no symptoms from it (i.e., they are asymptomatic) until fragments of the deposits fall off, lodge in the brain and cause a major stroke. The standard operation to prevent this, carotid endarterectomy (CEA), involves surgical removal of the deposits before they cause a stroke. It involves some immediate risk but if successful, confers long-term protection. An alternative technique is carotid artery stenting (CAS), which involves placing a fine scaffolding (stent) inside the narrowed artery to hold it open indefinitely. The aim of this study is to compare the immediate risks and long-term benefits of CAS and CEA for the prevention of stroke.

Who can participate?
Asymptomatic carotid artery stenosis patients in need of some type of carotid artery treatment, but with substantial uncertainty about whether to treat with CEA or CAS.

What does the study involve?
Participants are randomly allocated to be treated with either CEA or CAS, and we compare the immediate hazards (mainly heart attack, stroke or death) and the stroke risks over the next few years. The type and severity of any strokes is also assessed.

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

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
April 2007 to January 2026

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Prof. Alison Halliday
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Study website
http://www.acst-2.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00883402

Secondary identifying numbers
HTA 06/301/233

Study information

Scientific Title

Asymptomatic Carotid Surgery Trial 2: an international randomised trial to compare carotid endarterectomy with carotid artery stenting to prevent stroke

Acronym
ACST-2

Study objectives
To compare:
1. The peri-procedural risks (within 30 days) of carotid endarterectomy (CEA) or carotid artery stenting (CAS)
2. The long-term (5-year) prevention of stroke and of disabling or fatal stroke

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval for the lead centre (St George's, University of London): Hertfordshire 1 Ethics Committee, 11/10/2005, ref: 05/Q0201/66
All other centres have obtained ethics approval before recruitment of the first participant

Study design
International randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: https://acst-2.org/Patient%20Information/Patient%20Information%20Leaflet.html

Health condition(s) or problem(s) studied
Stroke caused by stenosis in the carotid arteries

Interventions
Carotid endarterectomy versus carotid artery stenting

Intervention Type
Procedure/Surgery

Primary outcome measure

1. Peri-procedural hazards (within 30 days) stroke, myocardial infarction and death
2. Long-term hazards (after 30 days) stroke and death

Secondary outcome measures
Cost-effectivness of CEA and CAS

Overall study start date
01/04/2007

Completion date
01/01/2026

Eligibility

Key inclusion criteria
1. Patient in need of some type of carotid artery intervention, with substantial uncertainty about whether to treat with CEA or CAS
2. Carotid artery stenosis with no ipsilateral carotid territory symptoms within the last 6 months
3. Patient fit and willing for follow-up

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
At least 5000 patients

Total final enrolment
3625

Key exclusion criteria
1. Previous CEA or CAS in randomised artery
2. High risk of adverse events of trial treatment e.g. inaccessible stenosis
3. Small likelihood of worthwhile benefit e.g. low risk of stroke
4. Patient unable or unwilling to give informed consent

Date of first enrolment
01/04/2007

Date of final enrolment
28/01/2021

Locations

Countries of recruitment

Belgium

Bulgaria

Canada

China

Czech Republic

Egypt

England

Estonia

France

Germany

Greece

Hungary

Ireland

Israel

Italy

Japan

Kazakhstan

Netherlands

Norway

Poland

Russian Federation

Serbia

Slovakia

Slovenia

Spain

Sweden

Switzerland

United Kingdom

United States of America

Study participating centre
University of Oxford
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Clinical Trials and Research Governance
Manor House
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Sponsor type
University/education

Website
http://www.admin.ox.ac.uk/rso/contactus/ctrg.shtml

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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?
Protocol article	protocol	01/08/2009		Yes	No
Results article	results	01/11/2013		Yes	No
Results article		27/08/2021	02/09/2021	Yes	No