

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	☒ Prospectively registered ☒ Protocol
Registration date 03/07/2006	Overall study status Ongoing	☐ Statistical analysis plan ☒ Results
Last Edited 20/01/2026	Condition category Circulatory System	☐ 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 December 2026

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

Who is the main contact?
Prof. Alison Halliday
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00883402

Protocol serial number
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

Primary study design

Interventional

Study design

International randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Cost-effectiveness of CEA and CAS

Completion date

31/12/2026

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Belgium

Bulgaria

Canada

China

Czech Republic

Egypt

Estonia

France

Germany

Greece

Hungary

Ireland

Israel

Italy

Japan

Kazakhstan

Netherlands

Norway

Poland

Russian Federation

Serbia

Slovakia

Slovenia

Spain

Sweden

Switzerland

United States of America

Study participating centre

University of Oxford

Richard Doll building, Old Road Campus, Roosevelt Dr, Headington

Oxford

England

OX3 7DQ

Sponsor information

Organisation

University of Oxford (UK)

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

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

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2013		Yes	No
Results article		27/08/2021	02/09/2021	Yes	No
Protocol article	protocol	01/08/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes