

# Asymptomatic Carotid Surgery Trial (ACST-1)

<b>Submission date</b> 23/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2018	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Carotid stenosis is a condition where one or both of the carotid arteries (the main blood vessels that supply the head and neck) become narrowed due to a build-up of fatty deposits (plaque). This increases the risk of having a stroke, when the blood supply to part of the brain is cut off. The aim of this study is to compare carotid surgery (carotid endarterectomy or CEA) with the best medical treatment (BMT) in patients with carotid stenosis but no symptoms. The aim of this study is to find out whether CEA and BMT together improve stroke-free survival time when compared to BMT alone. The study also aims to identify high-risk groups for whom the benefits of surgery and of BMT are increased and the long-term follow-up is looking at whether carotid endarterectomy reduces the risk of dementia in the long-term.

### Who can participate?

Patients whose carotid stenosis has not caused symptoms for at least 6 months, and who have no past history of stroke

### What does the study involve?

Participants are randomly allocated to be treated with either CEA plus BMT or BMT alone, unless symptoms develop requiring a CEA. Fatal and non-fatal stroke and death rates are compared between the two groups. For long-term follow-up the UK and Swedish participants' health records are also analysed for rates of stroke, death and dementia in the long-term. Relatives or friends of the UK participants are also asked to complete a postal questionnaire about the participant's cognitive (mental) function.

### What are the possible benefits and risks of participating?

There is no direct benefit to taking part but the information gained may help doctors to treat patients with asymptomatic carotid disease better in the future. There is no additional risk to taking part in this study. Long-term follow-up: there is no direct benefit to taking part but this follow-up may contribute to a wider benefit if carotid surgery is found to reduce the risk of developing later memory and thinking problems. The long-term follow-up does not involve any additional physical risk to the participants or does not provide any risk in relation to loss of anonymity.

### Where is the study run from?

John Radcliffe Hospital (UK)

When is the study starting and how long is it expected to run for?  
April 1993 to October 2019

Who is funding the study?

1. Medical Research Council (MRC) (UK)
2. Alzheimer's Society (UK)

Who is the main contact?

Alison Halliday  
acst@nds.ox.ac.uk

### **Study website**

<http://acst-2.org/acst-1%20long%20term%20follow-up.html>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Prof Alison Halliday

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Public

### **Contact name**

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
G9408332

## **Study information**

### **Scientific Title**

Asymptomatic Carotid Surgery Trial (ACST-1)

### **Acronym**

ACST-1

### **Study objectives**

The aim is to determine whether CEA and BMT improve stroke-free survival time when compared to BMT alone. The trial will also help identify high-risk groups in whom the benefits of surgery and of BMT would be increased.

Added 21/02/2017:

Primary objective: In participants with carotid stenosis, does carotid endarterectomy reduce the long-term risk of dementia, stroke or death related to carotid stenosis?

Secondary objective: In patients with carotid stenosis, does the long-term risk of dementia, stroke or death in recorded electronic records vary by duration of follow up, or participant characteristic recorded at baseline?

Updated 28/09/2018:

Primary objective: In participants with asymptomatic carotid stenosis, does carotid endarterectomy reduce the long-term risk of stroke, dementia or death, related to carotid stenosis?

Secondary objective: In patients with carotid stenosis, does the long-term risk of dementia or stroke in recorded electronic health records vary by duration of follow-up, or participant characteristic recorded at baseline?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

London Research Ethics Committee, 11/11/1998, ref: 98/2/92

**Study design**

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 contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Carotid stenosis

**Interventions**

CEA and best medical treatment (BMT) vs BMT alone

Added 19/08/2008: follow-up is a minimum of 5 years

Added 21/02/2017:

No further treatment interventions are planned as part of the long-term follow-up study.

Phase 1: Analysis of long-term data from UK and Swedish ACST-1 participant's health records through electronic data linkage (NHS digital, UK; Socialstyrelsen, Sweden) for specific outcomes of incident stroke, death and dementia (16/SC/0406). The trialists will also be applying to the equivalent regulatory authorities in Scotland and Northern Ireland.

Phase 2: A relative or friend of the ACST-1 UK participants will be invited to complete a postal questionnaire (Informant Questionnaire on Cognitive decline in the Elderly-IQCODE) on the participant's cognitive function.

Updated 28/09/2018:

No further treatment interventions are planned as part of the long-term follow-up study.

Phase 1: Phase 1: Analysis of long-term data from UK and Swedish ACST-1 participant's health records through electronic data linkage (NHS digital, UK; Socialstyrelsen, Sweden) for specific outcomes of incident stroke and dementia (ethics approved 16/SC/0406).

Phase 2: A relative or friend of the ACST-1 UK participants will be invited to complete a postal questionnaire (short form of the validated 'Informant Questionnaire on Cognitive decline in the Elderly' - IQCODE) on the participant's cognitive function.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Fatal and non-fatal stroke and death rates

Added 10/03/2017:

Long-term follow-up to determine specific outcomes of stroke and cognitive decline:

1. Long-term risk of dementia, stroke or death, measured using participant's health records through electronic data linkage (NHS digital, UK; Socialstyrelsen, Sweden) at least 14 years post enrolment
2. Cognitive function, measured using the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE), MoCA and TICS-N, at least 14 years post enrolment

Updated 28/09/2018:

Long-term follow-up to determine specific outcomes of stroke and cognitive decline:

1. Long-term risk of dementia, stroke or death, measured using participant's health records through electronic data linkage (NHS digital, UK; Socialstyrelsen, Sweden) at least 14 years post enrolment
2. Cognitive function, measured using the short form of the validated Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE), at least 14 years post enrolment

### **Secondary outcome measures**

Subsidiary analyses in an effort to identify high and low risk groups will include the effect of risk factors such as presence or absence of silent cerebral infarction on clinical outcome

### **Overall study start date**

01/04/1993

### **Completion date**

01/10/2019

## **Eligibility**

### **Key inclusion criteria**

1. Patients whose carotid stenosis has not caused symptoms for at least 6 months
2. No past history of ipsilateral disabling or severe contralateral stroke
3. No clear indications or contraindications to carotid endarterectomy (CEA)

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

3120; 1601 for long-term follow-up

### **Key exclusion criteria**

1. Patients with a small likelihood of worthwhile benefit e.g. those with major life-threatening disease.
2. Patients who have had recent myocardial infarct, intracerebral neoplasia or aneurysm, or restenosis of an artery following previous CEA

**Date of first enrolment**

19/04/1993

**Date of final enrolment**

01/05/2003

## **Locations**

**Countries of recruitment**

Austria

Belgium

Brazil

Bulgaria

Canada

Croatia

Cyprus

Czech Republic

England

Finland

France

Germany

Greece

Hungary

Ireland

Israel

Italy

Netherlands

New Zealand

Norway

Poland

Portugal

Russian Federation

Slovenia

Spain

Sweden

Switzerland

Tunisia

United Kingdom

United States of America

**Study participating centre**

**John Radcliffe Hospital**

Oxford

United Kingdom

OX3 9DU

**Study participating centre**

**123 other centres**

United Kingdom

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## **Sponsor information**

**Organisation**

Medical Research Council (MRC) (UK)

**Sponsor details**

20 Park Crescent

London

United Kingdom

W1B 1AL

+44 (0)20 7636 5422

[clinical.trial@headoffice.mrc.ac.uk](mailto:clinical.trial@headoffice.mrc.ac.uk)

**Sponsor type**

Research council

**Website**

<http://www.mrc.ac.uk>

**Organisation**

University of Oxford

**Sponsor details**

Research Services

Clinical Trials and Research Governance (CTRG)

Joint Research Office

1st Floor, Boundary Brook House

Churchill Drive

Headington

Oxford

England

United Kingdom

OX3 7GB

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[ctrig@admin.ox.ac.uk](mailto:ctrig@admin.ox.ac.uk)

**Sponsor type**

University/education

**Website**

<https://researchsupport.admin.ox.ac.uk/ctrig>

**Organisation**

University of Oxford

**Sponsor details****Sponsor type**

Not defined

**Website**

<http://www.ox.ac.uk/>

**ROR**

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

**Funder(s)****Funder type**

Research council



**Funder Name**

Medical Research Council (MRC) (UK)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Alzheimer's Society

**Alternative Name(s)**

alzheimerssoc

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Associations and societies (private and public)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

The long-term follow-up results are anticipated to be presented at relevant scientific forums and conferences in the spring 2019 and published end of 2019 in peer-reviewed scientific journals.

**Intention to publish date**

31/10/2019

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available.

**IPD sharing plan summary**

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	08/05/2004		Yes	No
<a href="#">Results article</a>	results	25/09/2010		Yes	No
<a href="#">Results article</a>	results	01/06/2013		Yes	No
<a href="#">Results article</a>	results	01/05/2016		Yes	No
<a href="#">Results article</a>	results	01/12/2016		Yes	No
<a href="#">Results article</a>	results	01/12/2016		Yes	No
<a href="#">Results article</a>	results	01/12/2016		Yes	No