ISRCTN26156392 https://doi.org/10.1186/ISRCTN26156392

Asymptomatic Carotid Surgery Trial (ACST-1)

Submission date
23/10/2000

Recruitment status
No longer recruiting

Registration date
23/10/2000

Overall study status
Completed

Last Edited
02/10/2018

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

ORCID ID
http://orcid.org/0000-0001-9828-3579

Contact details
ACST Trials Office
Level 6, West Wing
John Radcliffe Hospital
Headley Way
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 617975
acst@nds.ox.ac.uk

Type(s)
Public

Contact name
Ms Mary Sneade

ORCID ID
http://orcid.org/0000-0002-8860-0363

Contact details
ACST trials office
Richard Doll Building, Old Road Campus
Roosevelt Drive
Oxford

United Kingdom
OX3 7LF
+44 (0)1865 617978
acst@nds.ox.ac.uk

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
-

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

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
-
ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
https://researchsupport.admin.ox.ac.uk/ctrg

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?
Results article	results	08/05/2004		Yes	No
Results article	results	25/09/2010		Yes	No
Results article	results	01/06/2013		Yes	No
Results article	results	01/05/2016		Yes	No
Results article	results	01/12/2016		Yes	No
Results article	results	01/12/2016		Yes	No
Results article	results	01/12/2016		Yes	No