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Coronary Artery Bypass graft surgery in patients with asymptomatic carotid stenosis

Submission date
07/09/2010

Recruitment status
Stopped

Registration date
25/10/2010

Overall study status
Completed

Last Edited
26/10/2022

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
Coronary artery stenosis is a blockage of the arteries that supply blood to the heart muscle. It can be treated with a coronary artery bypass graft (CABG), which is a surgical procedure that diverts blood around the blocked part of the artery, or a carotid endarterectomy (CEA), which is a surgical procedure to unblock the artery. The aim of this study is to compare the safety and effectiveness of CABG alone versus CABG and CEA together in patients with coronary artery stenosis.

Who can participate?
Patients aged over 18 with coronary artery stenosis

What does the study involve?
Participants are randomly allocated to be treated with CABG either with or without CEA. The rates of non-fatal strokes or deaths are measured in both groups within 30 days after the surgery. Participants are followed-up for 1 year (including a physical and an ultrasound examination) with an additional yearly telephone follow-up for up to 5 years.

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

Where is the study run from?
University Hospital Essen (Germany)

When is the study starting and how long is it expected to run for?
September 2010 to December 2019

Who is funding the study?
Deutsche Forschungsgemeinschaft (Germany)

Who is the main contact?
Prof. Christian Weimar
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Study website
http://www.cabacs.de

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Coronary Artery Bypass graft surgery in patients with Asymptomatic Carotid Stenosis: a randomised controlled open multicentre group sequential trial with two parallel groups and blinded observers

Acronym
CABACS

Study objectives
The objective of this study is to compare the safety and efficacy of isolated coronary artery bypass graft (CABG) versus synchronous CABG and carotid endarterectomy (CEA) in patients with asymptomatic coronary artery stenosis (CAS) greater than or equal to 80% according to the European Carotid Surgery Trial (ECST) criteria.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Institutional Review Board (IRB) of the Medical Faculty of Essen, 05/08/2010, ref: 10-4325

Study design
Randomised controlled open multicentre blinded parallel-group sequential trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Coronary heart disease, carotid artery stenosis

Interventions
CABG with or without CEA must be performed as soon as possible (max. within 7 days) after randomisation. All patients will be treated with up-to-date medication following national and international guidelines. Recommendations for this treatment are provided by the 'Best Medical Treatment' subcommittee. Standards for surgical treatment have been formulated by the Surgical quality sub-committee. Aspirin (or clopidogrel) has to be applied before CABG as well as after surgery. All participating centres of cardiothoracic surgery are obligated to participate in a national quality management register. All participating surgeons have to meet the following standards:
1. Anonymous confirmation of the last 30 consecutively performed CEA, affirmed by the head of department
2. Anonymous confirmation of the last 150 consecutively performed CABG, affirmed by the head of department

Follow-up duration will be 1 year (including physical and ultrasound examination) with an additional yearly telephone follow-up up to 5 years after the intervention.

Intervention Type
Procedure/Surgery

Primary outcome measure
The primary efficacy and safety endpoint is the event rate of nonfatal strokes or deaths from any cause (whatever occurs first) within 30 days after the intervention (either isolated CABG or synchronous CABG + CEA).

Secondary outcome measures
1. Number of ischemic strokes ipsilateral to the initially higher grade, not occluded stenotic carotid artery within 30 days and 1 year
2. Any stroke or vascular death within 30 days, 1 year and 5 years
3. Deaths from any cause within 30 days, 1 year and 5 years
4. Number of disabling strokes (definition: stroke with resulting impairment >3 on the modified Rankin Scale) within 30 days and 1 year
5. Change of cognitive performance on the Demtec scale from randomization to 30 days and 1 year
6. Technical failure of intervention
7. Number of myocardial infarctions within 30 days, and from 30 days to 1 year
8. Duration of ventilatory support after operation (CABG ± CEA)
9. Total length of hospital stay and German diagnosis related group (G-DRG) for acute hospital stay
10. Total length of ICU stay

Overall study start date
15/09/2010

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Subjects meeting all of the following criteria will be considered for admission to the trial:
1. Asymptomatic (past 180 days) stenosis greater than or equal to 80% (following criteria of the ECST of the extracranial carotid artery in patients scheduled for CABG)
2. Negative pregnancy test in pre-menopausal women
3. Written informed consent and full legal capacity
4. Carotid stenosis treatable with CEA
5. Ability of the patient to participate in follow-up examinations
6. Aged greater than or equal to 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
316

Total final enrolment

Key exclusion criteria

Current exclusion criteria as of 09/04/2013:
Subjects presenting with any of the following criteria will not be included in the trial:
1. Non-atherosclerotic stenosis (e.g. dissection, floating thrombus, fibromuscular dysplasia, tumor)
2. Complete occlusion of the carotid artery to be treated
3. Prior stenting of the carotid artery to be treated
4. Stenosis following radiotherapy
5. Additional higher grade intracranial or intrathoracic stenosis (tandem stenosis)
6. Recent (past 180 days) ischemic symptoms ipsilateral to carotid stenosis or occlusion
7. Contralateral carotid occlusion or other known indication for carotid revascularization (apart from scheduled CABG)
8. NSTEMI within the past 48 hours, STEMI within the past 7 days or hemodynamically unstable patients
9. Evidence for intracranial bleeding within the past 90 days
10. Modified Rankin Scale score >3 or severe aphasia
11. Patients unlikely to survive more than 1 year due to concomitant diseases
12. Planned combined cardiac valve replacement or any other cardiac surgery beyond CABG (+/- CEA) during the procedure
13. Major surgery (apart from study procedures) planned within 8 weeks from randomization
14. Participation in another clinical trial

Previous exclusion criteria until 09/04/2013:
Subjects presenting with any of the following criteria will not be included in the trial:
1. Non-atherosclerotic stenosis (e.g. dissection, floating thrombus, fibromuscular dysplasia, tumor)
2. Complete occlusion of the carotid artery to be treated
3. Prior stenting of the carotid artery to be treated
4. Stenosis following radiotherapy
5. Additional higher grade intracranial or intrathoracic stenosis (tandem stenosis)
6. Recent (past 180 days) ischemic symptoms ipsilateral to carotid stenosis or occlusion
7. Contralateral carotid occlusion or other known indication for carotid revascularization (apart from scheduled CABG)
8. Myocardial infarction (NSTEMI or STEMI) within the past 7 days or hemodynamically unstable patients
9. Known high risk for cardiogenic embolism requiring anticoagulation (mechanical heart valve, chronic atrial fibrillation, left ventricular thrombus, left ventricular aneurysm)
10. Evidence for intracranial bleeding within the past 90 days
11. Modified Rankin Scale score >3 or severe aphasia
12. Patients unlikely to survive more than 1 year due to concomitant diseases
13. Planned combined cardiac valve replacement or any other cardiac surgery beyond CABG (+/- CEA) during the procedure
14. Major surgery (apart from study procedures) planned within 8 weeks from randomization
15. Participation in another clinical trial

Date of first enrolment

01/12/2010

Date of final enrolment

19/12/2014

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Essen
Essen
Germany
45122

Sponsor information

Organisation
University Hospital Essen (Universitatsklinikum Essen) (Germany)

Sponsor details
Hufelandstr. 55
Essen
Germany
45122

Sponsor type
Hospital/treatment centre

Website
http://www.uk-essen.de

ROR
https://ror.org/02na8dn90

Funder(s)

Funder type
Research council

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)

German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/06/2012		Yes	No
Results article	5-year results	09/09/2022	12/09/2022	Yes	No
Results article		15/09/2017	26/10/2022	Yes	No