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Stent-protected angioplasty in asymptomatic carotid artery stenosis vs endarterectomy: two two-arm clinical trials

Submission date
07/11/2006

Recruitment status
No longer recruiting

Registration date
16/07/2007

Overall study status
Completed

Last Edited
20/09/2022

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
The aim of this study is to compare up-to-date medical (conservative) treatment (BMT) including lifestyle modification with carotid artery stenting (CAS) and carotid endarterectomy (CEA) in addition to those conservative treatments in the treatment of individuals with asymptomatic atherosclerotic carotid artery stenoses.

Who can participate?
Patients with asymptomatic stenosis of the extracranial carotid artery. Asymptomatic means without stroke or stroke-like symptoms attributable to the target stenosis within the previous 180 days.

What does the study involve?
Patients are allocated to one of the two substudies based on the decision of the including physician and the patient's preference: either CEA (SPACE2a substudy) or CAS (SPACE2b substudy). Patients in the SPACE2a study will be randomly allocated to receive either CEA + BMT or BMT alone, while those in the SPACE2b study will be randomly allocated to receive either CAS + BMT or BMT alone. BMT is defined as the best medical treatment of hypertension, blood glucose and hyperlipidemia according to current guidelines.

What are the possible benefits and risks of participating?
The benefit from every treatment is the proposed reduction of future cerebrovascular and cardiovascular events. Each treatment arm carries specific risks. Risks from the conservative treatment are mainly due to possible side effects of the medication. The most important risk of both CAS and CEA is the risk of periprocedural stroke.

Where is the study run from?
University hospitals of Heidelberg, Kiel and Munich (technical university).

When is the study starting and how long is it expected to run for?
Recruitment of subjects started in October 2009. The overall duration of the trial is expected to be about 9 years.

Who is funding the study?
German Research Council (Deutsche Forschungsgemeinschaft [DFG]), Germany.

Who is the main contact?
Prof. Werner Hacke
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Study website
http://www.space-2.de/de/home/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Stent-protected angioplasty in asymptomatic carotid artery stenosis vs endarterectomy: a randomised, controlled, open, multi-centre study

Acronym

SPACE-2

Study objectives
Current hypothesis as of 19/12/2013:
Two separate superiority trials of interventions versus best medical treatment (BMT) are designed. The decision for one type of intervention is made (carotid endarterectomy [CEA] = SPACE2a or carotid artery stenting [CAS] = SPACE2b) prior to randomization. In both studies (SPACE2a and SPACE2b) the interventional treatment groups (CEA and CAS) will be compared with best medical treatment (BMT) separately. In addition, data from the CEA and CAS groups will be compared in an explorative manner.

Protocol can be found at: http://www.space-2.de/de/service/03/

Previous hypothesis:
1. Superiority of stent-protected angioplasty or carotid endarterectomy (CEA) as compared to best medical treatment with respect to the composite primary endpoint
2. Stent-protected angioplasty is not inferior to carotid endarterectomy with respect to the composite primary endpoint

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the University of Heidelberg, 20/10/2008, ref: S-311/2008
2. Ethics Committee of the University of Heidelberg gave approval on change of study design (amendment 25.09.2012) on 04/04/2013

Study design
Randomised controlled open multi-centre study with two two-arm clinical trials

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at: http://www.space-2.de/downloads/SPACE-2%20Patienteninformation.pdf (German only)

Health condition(s) or problem(s) studied
Asymptomatic moderate to severe stenosis of the extracranial carotid artery

Interventions

Current interventions as of 19/12/2013:
Patients are allocated to one of the two substudies based on the decision of the including physician and the patient's preference: either CEA (SPACE2a substudy) or CAS (SPACE2b substudy). Patients in the SPACE2a study will be randomly allocated to receive either CEA + BMT or BMT alone, while those in the SPACE2b study will be randomly allocated to receive either CAS + BMT or BMT alone. BMT is defined as optimal medical treatment of hypertension, blood glucose and hyperlipidemia according to current guidelines.

Previous interventions:
1. BMT alone
2. Stent-protected angioplasty and BMT
3. Carotid endarterectomy and BMT

Intervention Type
Procedure/Surgery

Primary outcome measure
Cumulative rate of events consisting of:
1. Any stroke within 30 days of treatment
2. Death from any cause within 30 days
3. Ipsilateral ischaemic stroke within five years

Secondary outcome measures
1. All single components of the primary endpoint clusters
2. Any stroke, vascular death or myocardial infarction within 30 days (five years)
3. Any ischaemic stroke within 30 days (five years)
4. Disabling stroke within 30 days (five years)
5. Technical failure of intervention
6. Rate of re-stenosis (NASCET more than or equal to 50%)
7. Rate of myocardial infarction (30 days)

Overall study start date
01/03/2009

Completion date
12/12/2019

Eligibility

Key inclusion criteria
Sonographic identification of a more than or equal to 50% stenosis (North American Symptomatic Carotid Endarterectomy Trial [NASCET] criteria) of the extracranial carotid artery in a patient (both genders, age limit 85 years) without symptoms attributable to the target stenosis within the previous 180 days.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
2 x 1636

Total final enrolment
513

Key exclusion criteria
Non-atherosclerotic origin of carotid stenosis.

Date of first enrolment
09/07/2009

Date of final enrolment
12/12/2014

Locations

Countries of recruitment
Austria

Germany

Switzerland

Study participating centre
University of Heidelberg
Heidelberg
Germany
69120

Sponsor information

Organisation
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

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Sponsor type
Research council

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ROR
https://ror.org/018mejw64

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	01/08/2009		Yes	No
Results article	results	01/06/2016		Yes	No
Results article	results	15/03/2019	04/08/2020	Yes	No
Results article		01/10/2022	20/09/2022	Yes	No