

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/09/2022	Condition category Circulatory System	<input type="checkbox"/> 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

85 years

Sex

All

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)

ROR

<https://ror.org/018mejw64>

Funder(s)

Funder type

Research council

Funder Name

Deutsche Forschungsgemeinschaft

Alternative Name(s)

German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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
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