Status update SPACE II

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Prevalence of >50% carotid artery stenosis is high!

20% of ischemic strokes associated with carotid disease

based on former RCT’s CEA/CAS prophylactically in AsxCS

However since previous studies effectivity BMT / safety CEA and CAS have changed substantially
Asymptomatic Carotid Artery Stenosis Treated with Medical Therapy Alone

Cerebrovasc Dis 2014;38:163–173
DOI: 10.1159/000365206

2-3% spontaneous annual ipsilateral stroke rate AsxCS with BMT

0.5 -1%

Last recruitment year

Events per 100 person-years


Cerebrovascular Diseases

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Safety of CEA + CAS in trials and registries improved
Best treatment for Asx-CS at present?! 

national 3 armed government funded RCT
**Main question:** Are **CAS** or **CEA** superior to a **modern medical therapy** in primary prevention of an carotid-related ischemic stroke **within 5y**?
Recruitment insufficient:
- only 10% of pts randomized in 3 yrs
- only 44 centers, rather than 100 centers
a three-armed interventional RCT was not feasible!

3 arm RCT to complex pts. & doctors ?!

Interference with ACST 2 Trail ?!
Treatment of asymptomatic carotid artery stenosis. Improvement of evidence with new SPACE-2 design necessary

Two separate superiority-trials of interventions vs. BMT
SPACE 2 – new 2 arm design: PRO’s and Con’s

**Contra:**  - direct comparability CEA vs CAS not given

**PRO:**  - easier communication to pts + doctors
- increased number of pts. in BMT-group (50%)
- study centers with only one interventional discipline can enroll pts

Σ: recruitment rates increase with 2 arm design

pts. deemed unsuitable for SPACE 2 can randomized within ACST 2
Randomization between Sept 2009 and July 2014

- New study design
- Prior study design

only 513 pts. in September 2014
only 6 new centers
Progress Report to German Research Foundation (DFG)

- Recruitment rates by new SPACE design are only slightly increased.
- No. of study patients and no. of centers still too low.

DFG-Panel-Clinical Studies: Recommendation to stop recruitment despite:

- Clinical question of SPACE-2 still very important.
- SPACE-2 is well-designed and organized by experienced clinical researchers.

However: frame conditions in German hospitals do not support recruitment:
- Enormous numbers of patients treated outside the trial.
- Often due to economic reasons: BMT: ~ 0€, CEA/CAS: ~ 6000€.
Current situation and next steps

- Recruitment was stopped immediately
- 519 patients (406 from SPACE 2 and 113 from SPACE 2A and 2B)
  - CEA 207 pat, CAS 198 pat, BMT 114 pat
- Mean Follow-up about three years
- Follow-up will be completed up to 5 years for all patients
- Early results of this series will be published soon
- Data will be implemented in the CSTC database (Carotid Stenosis Trialist Collaboration)
Thank you for attention!

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