Status Of The SPACE-2 Trial: Although Patient Enrollment Has Been Stopped, What Useful Information Will It Provide?

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Main question:
Are CAS or CEA superior to a modern medical therapy in the primary prevention of a carotid-related ischemic stroke?

Key Inclusion and Exclusion Criteria
Atherosclerotic carotid stenosis ≥70% (ECST)
Age from 50 to 85 yrs.
No stroke or stroke-like symptoms within 180 days
Stenosis treatable with CEA and CAS
Preexisting disability (modified RS ≥ 2)
Radiation induced stenosis, recurrent stenosis
High grade tandem stenosis
Cardiac embolism source (atrial fibrillation, prosthetic heart valve)
Life expectancy < 5yrs.

The SPACE network and recruitment since 2009
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Two separate superiority-trials of interventions vs. BMT

Disclosures
- Research grants by MEDTRONIC and COOK
- Executive board of VASCULAR INTERNATIONAL
Randomization between Sept 2009 and July 2014 (513 pts)

22.10.2014: Decision of the German Research Society (DFG) not to fund for new patients, SC decided to stop inclusion of further patients

SPACE-2: demographics (preliminary)

why did we fail to recruit more patients?

- Political and economic frame conditions
  - hospitals need a balanced budget and urge doctors to generate "cases"
  - CAS is paid by health assurancies (even if evidence is missing)
- Surgeons and endovascular specialists
  - personal income might be affected
  - Weak academic tradition
- Referring physicians
  - expect their patients to be treated by CEA or CAS
  - Have advised their patients already
- Patients
  - don’t like it to be randomized
  - own perception what is best for them (Internet, etc)

Perspectives for SPACE 2

- Continuation of the follow up (5 yrs per patient) will be financed by the German Research Organisation
- Safety data will be published very soon (based on 513 pts)
- Pooling of the data with ACST-2, ECST-2, CREST-2 anticipated (as part of the Carotid Stenosis Trialist Collaboration, CSTC)
- Participation in ACST-2 or ECST-2 left to the discretion of the centers, but supported – in general – by the Steering Committee

Conclusions/Dilemma

- RCTs are difficult to perform (in Germany)
- Prospective registries: enough „evidence“?
- Access to new technologies (CAS) only in trials?

Thank you very much!
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