Status update on the ongoing trials looking at asymptomatic carotid stenosis

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Disclosure

Speaker name: Alison Halliday

I do not have any potential conflict of interest
Guidelines support the trials
Trials of CEA and CAS

Symptomatic
- Revascularisation needed, uncertain if CAS or CEA
  - CAS vs. CEA
    - EVA-3S, SPACE, ICSS, CREST-1

Symptomatic, 5-year risk <15%
- Revascularisation uncertain need
  - Revasc vs. BMT
    - ECST-2 (*pilot)

Asymptomatic
- Revascularisation needed, CAS or CEA?
  - CAS vs. CEA
    - CREST-1, ACT-1, SPACE-2, ACST-2

Revascularisation uncertain need
- Revasc vs. BMT
  - ECST-2 (*pilot)
  - ACST-1, SPACE-2, ECST-2*, CREST-2

CAS vs. CEA

Revasc vs. BMT

Network meta-analysis 6500 patients
Ongoing Trials of Asymptomatic stenosis
6500 patients

- **SPACE2** – complete, in follow up, 500 patients
  Tilman Reiff - presentation at Munich Conference, Dec 2018
  ‘Stroke and TIA rates at one year in SPACE-2: BMT vs. CEA versus CAS in asymptomatic carotid stenosis’

- **ECST-2** – pilot, 337 patients by 5/18 no results yet
  symptomatic or asymptomatic moderate or severe carotid stenosis at low or intermediate risk of future stroke

- **CREST 2** – recruiting, now 1266/2480 patients
  two trials (CEA vs Medical treatment alone, CAS vs same, funded to 4 yr f-up

- **ACST-2** – nearing completion 3160/3600
  CEA vs CAS in patients thought to need intervention
CREST 2 – about halfway there

CREST-2 Study Center Locations

To find a center near you, go to the Locations Page (/locations.html). Check back often for newly added states.

119 CREST-2 Centers
have enrolled a total of

1,266 of 2,480
CREST-2 Participants

CREST-2 is seeking 2,480 participants across the United States and Canada to be in this study.
ACST-2 trial (acst-2.org)

Asymptomatic Carotid Surgery Trial (ACST-2)

ACST-2 (ISRCTN21144362) is an international randomised trial, coordinated by The ACST-2 office at The University of Oxford, comparing carotid endarterectomy (CEA) with carotid stenting (CAS) for long-term stroke prevention.

Patients in ACST-2 have tight asymptomatic carotid stenosis. We are comparing both the immediate hazards of the procedures when carried out by experienced doctors and the subsequent stroke rates over the next 5 to 10 years.
ACST-2
33 countries, includes Brazil, Canada, China, Japan, Kazakhstan, USA, Argentina
<table>
<thead>
<tr>
<th>Mean follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEA: 4.0 person-years</td>
</tr>
<tr>
<td>CAS: 4.0 person-years</td>
</tr>
</tbody>
</table>

ACST-2 Recruitment target = 3600

3173 (88%)
ACST-2
CEA vs CAS

Collaborators are free to use their usual techniques

GA or LA; Primary or patch closure… Any CE marked stent. CPD not mandated
ACST-2 Medical therapy at Entry

- 81% lipid-lowering drugs
- 85% anti-hypertensive therapy
- 96% anti-thrombotic (anti-platelet/anti-coagulant)

Good long-term compliance (drugs + doses ascertained yearly)
<table>
<thead>
<tr>
<th>Anaesthetic</th>
<th>GA (60%)</th>
<th>LA (40%)</th>
<th>Total (n=1434)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patch</td>
<td>52%</td>
<td>29%</td>
<td>43%</td>
</tr>
<tr>
<td>Shunt use</td>
<td>28%</td>
<td>8%</td>
<td>20%</td>
</tr>
</tbody>
</table>
# Modern CAS therapy in ACST-2: Dec 2018

## Stent use

<table>
<thead>
<tr>
<th>Stent Type</th>
<th>Use (%)</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wallstent (Closed)</td>
<td>44%</td>
<td>355</td>
</tr>
<tr>
<td>Xact</td>
<td></td>
<td>218</td>
</tr>
<tr>
<td>Adapt</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Precise (Open)</td>
<td>33%</td>
<td>178</td>
</tr>
<tr>
<td>Protégé® RX</td>
<td></td>
<td>127</td>
</tr>
<tr>
<td>RX Acculink</td>
<td></td>
<td>120</td>
</tr>
<tr>
<td>ViVEXX</td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Zilver</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>Cristallo Ideale (Hybrid)</td>
<td>14%</td>
<td>175</td>
</tr>
<tr>
<td>Sinus Carotid Conical RX</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Mer</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Roadsaver (Membrane)</td>
<td>9%</td>
<td>79</td>
</tr>
<tr>
<td>CGuard</td>
<td></td>
<td>42</td>
</tr>
</tbody>
</table>

## CPD use

<table>
<thead>
<tr>
<th>CPD Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter (68%)</td>
<td></td>
</tr>
<tr>
<td>Filterwire</td>
<td>285</td>
</tr>
<tr>
<td>Emboshield</td>
<td>275</td>
</tr>
<tr>
<td>Spider</td>
<td>214</td>
</tr>
<tr>
<td>Accunet</td>
<td>77</td>
</tr>
<tr>
<td>AngioGuard</td>
<td>49</td>
</tr>
<tr>
<td>FiberNet</td>
<td>1</td>
</tr>
<tr>
<td>Wirion System</td>
<td>1</td>
</tr>
<tr>
<td>Proximal occlusion (17%)</td>
<td></td>
</tr>
<tr>
<td>Moma</td>
<td>193</td>
</tr>
<tr>
<td>Gore Flow Reversal T CAR</td>
<td>28</td>
</tr>
<tr>
<td>Distal balloon (&lt;1%)</td>
<td></td>
</tr>
<tr>
<td>Twin One</td>
<td>6</td>
</tr>
<tr>
<td>Viatrac</td>
<td>2</td>
</tr>
<tr>
<td>None (15%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1331</td>
</tr>
</tbody>
</table>
ACST-2 Procedural hazards (CEA+CAS) much lower than symptomatic trials

Disabling and fatal Stroke ≤ 30 days

1.0%

Lower than in previous trial of CEA:

1.7% (ACST-1)

Procedural competence, interventions are low-risk
ACST-2 and stenting safety

• Medical therapy in ACST-2 is good (>80%)
  Moderate and high statin regimens favoured

• Cerebral protection widely used (85%)

• Flow reversal quite common (17%)
  Mo.Ma often used

• Closed cell stents still predominate (44%)
  Membrane-mesh covered stents emerging
ACST-2 results expected 2021

427 more Patients needed!
2017 Carotid and Vertebral Artery Disease: Follow the Guidelines – randomise!

Guidelines support these trials!
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