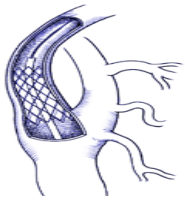
Asymptomatic Carotid Stenosis Trial-2 (ACST-2) SUMMARY PROTOCOL



ELIGIBILITY

- All patients, high or low risk, with asymptomatic carotid stenosis & other stroke risk factors appropriately treated
- Doctor & patient **substantially uncertain** about whether Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) is the best option
- No definite indications for or contraindications to either procedure
- Patient fit & willing for 5-year follow-up

ENTRY

- Obtain written patient consent to take part in ACST-2 & Blood Spot - place Blood Spot patch in plastic envelope on Consent Form
- Complete one-sided Randomisation Notepad
- Ring 24-hour randomisation service: +44(0)1865 765615 for treatment allocation (CEA or CAS) & patient identification number
- Send Consent Form, Blood Spot & Randomisation Notepad to CTSU in FREEPOST envelope

PROCEDURE & FOLLOW-UP

- Carry out allocated treatment (CEA or CAS) as soon as possible
- Measure Troponin-T 8-24 hrs after procedure
- Arrange (a) post-procedure duplex ultrasound to check carotid artery patency & (b) 1-month clinical follow–up
- Major Events (myocardial infarction, stroke, death) sent to ACST-2 office

Long-term annual follow-up organised by ACST-2 office directly with patient

24-hour randomisation telephone:+44 (0) 1865 765615
ACST-2 office telephone:+44 (0) 20 8725 3746
Fax:+44 (0) 20 8725 3782 Email: acst@sgul.ac.uk
Website:www.acst.org.uk/

Not eligible if contralateral carotid artery has been randomised in ACST-2 or if ipsilateral artery has already had CEA or CAS.

Other reasons for not entering patients into ACST-2 specified not by the protocol but by the responsible doctor, might include:

- either only a small likelihood of worthwhile benefit
  - Very low risk of stroke (e.g. very minor stenosis)
  - Some major life-threatening disease (e.g. advanced cancer)

-or a high risk of adverse events of trial treatment:

- inaccessible stenosis (e.g. at carotid siphon)
- unfit for surgery (e.g. severe heart failure)