



# Asymptomatic Carotid Surgery Trial



## ACST-2 PROTOCOL SUMMARY

### ELIGIBILITY (potential, then definite)

- **Potential eligibility:** Asymptomatic carotid stenosis that may well need procedural treatment with either carotid endarterectomy (CEA) or carotid artery stenting (CAS) The study can be mentioned and the ACST patient information leaflet given (or re-offered) either as soon as stenosis is found, or after further investigations, or both
- No symptoms from the stenosis (or none for some months), and no procedure previously performed on it. Any medical treatment (eg, statin, aspirin etc) already started; patient already recovered from any necessary coronary procedures (eg, CABG)
- **Definite eligibility:** MRA, CTA or other angiogram shows that CEA and CAS are both practicable: doctor **substantially uncertain** whether CEA or CAS is better, and sees no definite indication/contraindication for either \*

### INFORMATION LEAFLET (can be re-offered) & consent

- Potentially and definitely eligible patients: mention the study and give (or re-offer) information leaflet (with an ACST doctor's name written onto the consent form) for the patient to read and discuss now and/or take away to consider and discuss later
- If the patient is then also **substantially uncertain** between CEA and CAS and is willing and eligible to join ACST, invite witnessed signature of the consent form
- Consent requires address of patient (for annual follow-up letter), of family doctor and of 1 or 2 friends or relatives (in case contact is lost). The information leaflet asks the patient to bring these along, but clinic staff may need to help the patient get them fully completed

### ENTRY (by telephone randomisation)

- Complete at least part 1 of the randomisation form before telephoning to enter the patient, as these details are needed in the phone call. (The rest can be done later)
- Ring the randomisation service +44 (0)18 65 76 56 15 to obtain the treatment allocation (CEA/CAS) and a 6-digit patient ID number
- Tell the patient which procedure (CEA/CAS) they have been allocated, and plan for that procedure to be done as soon as possible

### PROCEDURE (performance, and 1-month follow-up)

- A collaborator with an approved Track Record for performing the allocated procedure does it, using their normal CEA/CAS techniques (& approved materials)
- Before discharge, schedule a follow-up about 1 month later for:
  - duplex ultrasound (to check carotid patency)
  - examination by neurologist/stroke physician (to assess & describe any peri-or post-operative stroke or MI)
- Complete and return the 1-month post-procedural form (stroke, MI or death); routine annual follow-up is then by letters to the patient from the ACST office

Randomisation: telephone +44 (0) 18 65 76 56 15

Website: [www.acst-2.org](http://www.acst-2.org)

\* Reason for not randomising are specified not by the protocol but by the responsible doctor, and might include

- either only a small likelihood of worthwhile benefit	-or a high risk of adverse events from CEA or from CAS
● Very low risk of stroke (eg, very minor stenosis)	● Access anatomically difficult either for CEA or for CAS
● Some major life-threatening disease (eg, advanced cancer)	● Unfit for surgery (eg, severe heart failure)