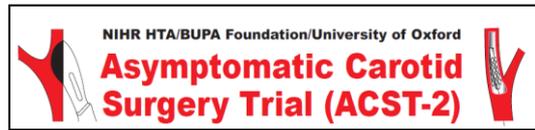


## Recruitment 'tips'



Please try to approach patients about ACST-2 if they:

- Have a tight carotid artery stenosis, confirmed by duplex ultrasound
- Have had no ipsilateral carotid territory symptoms for six months
- Are likely to live for a minimum of five years

The rest of this document includes suggestions that may help with recruitment and informed consent to the ACST-2 study. They are based on data from audio-recorded appointments and interviews with recruiters. You may wish to consider using some of these suggestions alongside your own individual style.

### Starting the appointment and describing the ACST-2 study

It is helpful for patients if you describe the ACST-2 study as early in the appointment as possible – as a study (avoid using the term 'trial'). It is important to...

- Explain why the patient had a carotid scan and indicate the degree of stenosis, including that:
  - their stenosis is significant, leading to a 1-2% risk of having a stroke each year
  - they will be put on appropriate medical therapy
- Explain that an intervention alongside medical therapy could further reduce the long-term risk of stroke by half.

### Describing the treatment arms and the ACST-2 study

It is helpful if you inform the patient that...

- They may be suitable for either stenting or surgery, and that both procedures are well-established (avoid saying one is 'standard' and the other 'different' or 'experimental'). See Table overleaf for treatment details.
- Both treatments unblock the narrowing and have been shown to be effective in reducing the risk of stroke, but we do not have evidence to show which one is best. You could say:

*'There is no strong evidence to date to suggest which treatment, stenting or surgery, is better – so we are running a research study called ACST-2 to help us find out the answer. I will explain the study and the two treatments in detail so that you can decide whether or not to take part. Please try to keep an open mind about these treatments until you have heard all the information.'*

- If they agree to join the ACST-2 study, they will have an equal chance of having either of these two well-established treatments. One way to explain this is to say:

*'The only way to find out which of these procedures is best is through a process called randomisation. This means that you will be assigned to one of the procedures by chance. You would not choose and neither would I. This is so that the two groups will be as similar as possible in all other respects, so that the procedures can be compared with each other as fairly as possible.'*

It is helpful to avoid using terms such as 'toss of a coin' or 'decided by a computer' to explain randomisation.

### Responding to patient questions and preferences

It is helpful if you...

- Present the study in an enthusiastic and straight-forward manner, without apologising. You can explain the benefits of study participation - for example, the close follow-up and monitoring, and that the aim of ACST-2 is to produce evidence so that future patients will not have to face current treatment uncertainties.
- Find out the reasons why a patient prefers one option over the other. This will enable you to be sure that they understand the issues and have not misunderstood or been misinformed.

### Closing the appointment

- Encourage the patient to ask questions about the ACST-2 study and the treatments available for their stenosis.
- Offer the patient the opportunity to take part in the study and be entered if they are uncertain about whether they should have a stent or surgery.
- Arrange, if not already done, for the patient to have some type of angiography (e.g. MRA or CTA) to ensure the patient is suitable for both CEA & CAS.
- When patients consent to join the study and you have completed the randomisation, it is important to organise the next appointment and focus discussion on issues related to their allocated treatment.

*Thank you for your commitment to ACST-2*

**Table of advantages and disadvantages of treatment in ACST-2**

	<b>Carotid stenting</b>	<b>Carotid endarterectomy</b>
<b>Possible advantages</b>	<ul style="list-style-type: none"> <li>○ Reduces risk of future stroke</li> <li>○ Usually shorter hospital stay</li> </ul>	<ul style="list-style-type: none"> <li>○ Reduces risk of future stroke</li> <li>○ Local hospital can often provide the procedure</li> </ul>
<b>Possible disadvantages</b>	<ul style="list-style-type: none"> <li>○ Small risk of having a stroke or heart attack (less than 1 in 100) and wound infection (less than 1 in 100)</li> <li>○ Bruising and soreness for a few days where stent was inserted</li> <li>○ You may need to travel to nearby hospital to have procedure</li> </ul>	<ul style="list-style-type: none"> <li>○ Small risk of having a stroke or heart attack (less than 1 in 100) and wound infection (less than 1 in 100)</li> <li>○ Discomfort and/or numbness around the neck for a few days, and possible hoarse voice. Small scar on the neck (around 7-10cm)</li> <li>○ Usually longer hospital stay</li> </ul>

**Would you like help with recruitment?**

Thank you to those who are participating in the ACST-2 QRI (Qualitative Recruitment Investigation). This includes recording consultations where ACST-2 is discussed with patients. We have successfully employed these methods in many RCTs (23 total, including 9 ongoing) by understanding how the study is discussed with patients and helping to find the most effective ways to present it to patients to optimise their understanding. The QRI team is also able to provide personalised, confidential feedback to those who record their appointments (only a few recordings are needed, and audio equipment/instructions will be provided).

Contact [daisy.townsend@bristol.ac.uk](mailto:daisy.townsend@bristol.ac.uk) for more information.