

# ACST-2 patient information leaflet

## Information about a research study that you may be invited to join

Patients who have a narrowing in one of the arteries that takes blood to the brain may need something done to keep that artery open (even if the narrowing has not caused a stroke, or any other symptoms). There are two main ways of doing this (called carotid endarterectomy [CEA] or carotid artery stenting [CAS]), but they cannot both be done at the same time on the same narrowed artery. If (maybe after further tests) your doctor is still **uncertain** which of these two procedures to recommend for you, then you may be invited to join an international study comparing them.

This information leaflet describes that study. Briefly, half the patients who join it get CEA, half get CAS, and after the allocated procedure has been done we send you, once a year for at least 5 years, a short questionnaire asking how you have been. If you are invited to join, and agree to do so, then we would need not only your own name and address but also (in case we lose contact) that of your family doctor and of 1 or 2 friends or relatives – please let them know that you've given us their details. Thank you for taking the time to read this.



Dr. Alison Halliday, study director  
University of London

PS. There are no payments to doctors or patients who join this study, and the eventual results will be freely available to help future patients.

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***Main information on inner pages...***

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**Notes to doctors: Please see back cover**

# Possibility of joining a large international study comparing 2 stroke prevention procedures (CEA & CAS)

**Before you consider whether to join we would like to summarise why this study is being done and what it will involve. Please discuss this if you wish with friends, relatives or your family doctor.**

- Your hospital doctor may already have told you that you are at increased risk of having a stroke because you have a narrowing in one or both of your carotid arteries (the arteries in the neck that supply blood to the brain). Although you don't have any symptoms at present, this narrowing may need to be treated promptly to reduce your risk of having a stroke over the next few years.
- The standard procedure ("**carotid endarterectomy**" - CEA) involves surgery, often under a general anaesthetic, to unblock the inside of the narrowed part of the artery in the neck. We know already that this operation involves some immediate risk, but that it does provide long-term protection against the narrowing causing a stroke.
- A newer procedure ("**carotid artery stenting**" - CAS) can now be used instead. This involves inserting a tube inside the narrowed part of the artery to hold it open. CAS avoids operating on the neck, as the tube is inserted via an artery some distance away (usually in the leg), often with only a local anaesthetic. CAS might be safer and as effective as CEA at preventing stroke, but currently there is not enough information to know this reliably.
- Your hospital doctor is at present uncertain which of these two procedures would be better for you. If any further tests leave the doctor still uncertain, and you too are uncertain, then please consider taking part in this research study (involving thousands of patients like you) to help find out which procedure is the safer and more effective at preventing stroke.
- If, on the other hand, you would definitely prefer CEA or would definitely prefer CAS (or would definitely prefer neither) then please do not join the study; just tell your doctors your wishes.

- Among those who do join the study, half will be allocated CEA, and half will be allocated CAS. Neither you nor your doctor (nor anyone else) will know beforehand which of these two procedures you will be allocated if you join. This will be determined by the play of chance (as if on the toss of a coin) once you join the study and information about you has been put into the study computer. When the procedure (CEA or CAS) has been allocated, your doctor should arrange for you to get it as soon as possible.
- All other aspects of your care will remain the responsibility of your own doctor, and will not be affected by you being in the study. You will be free to withdraw from the study at any time. If you do withdraw, this will not adversely affect your medical care. The patients (and their doctors) who take part in this study are not paid to do so, and participate freely.
- All the information collected about you during the study will be stored securely on UK University computers and kept strictly confidential. Any published reports of the study will not identify you or any other patients, and will be made publicly available on the study website.
- Your doctor will want to see you about 1 month after the procedure has been done to assess your general health. Then the study organisers would like to send you a brief questionnaire once a year for at least 5 years, probably by letter (or by telephone or email), to ask how you are doing.
- If you decide to take part, you will be asked to sign a consent form (on page 7 of this leaflet) saying that you agree to do so, and your family doctor will be sent a letter saying that you have done so.
- On the consent form you will be asked to give the contact details of your family doctor and of 1 or 2 friends or relatives, so we can ask them how you are if we lose contact with you. Please be ready to provide these details if you think you might join the study: see below.

**If you might decide to take part, please bring to your next clinic visit contact details of your family doctor and of 1 or 2 friends or relatives (or write them onto the consent form on page 7)**

***Extra details on next page for patients who want them***

# ACST-2: Second Asymptomatic Carotid Surgery Trial

## Extra details for patients who want them

**Background** Narrowing in the carotid arteries (the main arteries in the neck that supply blood to the brain), caused by build-up of fatty deposits, is a cause of many strokes. People with this narrowing may be asymptomatic – that is, they may have no symptoms until fragments fall off, lodge in the brain and cause a stroke. The standard procedure to prevent this, “carotid endarterectomy” (CEA), involves operating on the neck to remove the fatty deposits from the artery before they cause stroke-like symptoms or a major stroke. CEA involves some immediate risk but, if successful, provides long-term protection against the narrowing causing a stroke. An alternative procedure is “carotid artery stenting” (CAS), which involves placing a fine wire mesh tube (called a stent) inside the narrowed artery to hold it open. CAS avoids neck surgery, but we do not yet know how it compares with CEA in immediate risks or in long-term benefits, as previous studies comparing these procedures were too small.

**What is the study about?** ACST-1 (the first asymptomatic carotid surgery trial, 1993-2003) involved 3000 patients, and showed that CEA could be effective. ACST-2 will now involve many thousands of patients where both the patient and doctor are **substantially uncertain** whether to opt for CEA or for the newer procedure, CAS. Half of the patients will be allocated CEA and half CAS to treat the narrowed artery in their neck. The relatively small immediate hazards (mainly heart attack, stroke or death) and the small remaining stroke risks over the next few years after these 2 procedures will be compared, and the type and severity of any strokes that may occur will be assessed. This type of large, long-term study will help find out reliably which is the better treatment for future patients like you.

**What does the study involve?** If you agree to take part, you will be asked to sign a consent form (on page 7 of this information leaflet) and to give contact details of your family doctor and of two friends or relatives. If for some reason we lose contact with you over the next few years, we can then ask them how you are. You will be allocated to either CEA or CAS: this will be decided randomly and unpredictably by the central computer (as if on the toss of a coin). Your hospital doctor will then arrange for the allocated procedure to be carried out as soon as routinely possible. If after joining the study you later change your mind, then you are free to do so without needing to give any reason and without adversely affecting other aspects of your care. Your doctors will continue to see you as normal regardless of whether or not you join (or stay in) the study.

**What do the different procedures involve?** Whichever operation you have, the doctor treating you will be experienced in the technique and will carry it out according to the usual methods used in your hospital. If you have CEA, you may have a general anaesthetic, and you may have to stay in hospital for several days after surgery. If you have CAS, you will usually have a local anaesthetic and may well be able to go home the following day. If after you join the study your doctor decides for any reason that the allocated procedure no longer seems appropriate, you will be offered the other treatment option if it seems appropriate. This is up to your doctor, and is not controlled by the study.

**What will happen after the procedure?** You will be seen by a hospital doctor about 1 month after the procedure to

assess your general health. Then, every year for at least 5 years, the study organisers would like to send you a short questionnaire about whether you have had any problems possibly linked to your carotid artery (eg, whether you have had a stroke, and, if so, how this has affected you). Your normal medical care should not be affected by your participation in the study.

**Are there any risks?** Successful treatment of carotid narrowing will reduce the chance of you having a stroke from it in the future, but CEA and CAS themselves carry a relatively small risk of causing an immediate stroke or heart attack. But, your doctor would put you forward for these procedures only if your doctor thinks that, for you, the expected benefits are greater than the risks.

**What if something goes wrong?** In the event of you being harmed as a result of taking part in this research project, you will retain the same rights of care as any other patient, including access to the usual complaints mechanisms if something was done wrongly. Whilst there are no special compensation arrangements for participants, if you are seriously harmed due to someone’s negligence then you would, of course, have the usual grounds for taking legal action. You would receive the appropriate investigations, treatments and care, just like any other non-study patient.

**Who is organising the study?** The study is organised by the ACST office at St George’s University of London, working with the Clinical Trial Service Unit at the University of Oxford (the official sponsor of the study), and the running costs, for at least the first few years, are paid jointly by the UK government’s Health Technology Assessment Programme and a UK medical research charity, the BUPA Foundation. The hundreds of doctors and thousands of patients who participate in the study are not paid to do so (so you personally will gain nothing from joining), but the final results will be freely available to help future patients.

**When will it provide answers?** It will take some years to enrol enough patients to make the study large enough to be reliable, and these patients will then have to be followed up for some years after their treatment to compare the long-term effects of CEA and CAS. While the study is in progress its early findings (and any other new relevant information) will be continually monitored to ensure that the study remains appropriately safe and viable. Long after you join, the final results will be freely available on the study website and published in a scientific medical journal, but neither you nor other patients will be identified when this happens.

**Confidentiality** We want to collect only the information that is required to help compare CEA with CAS (although we may find we can also use this information for other medical research to help future patients). The information will be treated in strict confidence, held by the study organisers on secure databases on UK University computers, and retained for a minimum of 15 years. Your name, address and date of birth may be passed confidentially to a national records office to help us remain in touch with you, and your medical records may be inspected confidentially by trial regulators and other properly authorised persons to check that we are doing the study properly. Otherwise, any information released outside the trials office will not identify you.

**If anything is not clear, or you would like more information, please ask the doctor who gave you this leaflet or your family doctor, or another doctor (eg, the one named on the consent form); or, see [www.acst.org.uk](http://www.acst.org.uk)**

**If you do eventually decide to join, then the consent form on the next page is what you will be asked to sign. On it are the contact details that you will be asked for.**

**You will be offered this information leaflet to keep (with a copy of the completed and signed consent form as page 7 of it).**

**December 2007**



# ACST-2 patient information leaflet (last page) with consent form on previous page

## Notes to doctors

- This leaflet can generally be given even before it has been decided whether any carotid procedure will be needed, as soon as significant carotid artery narrowing has been detected (as long as this has caused no recent symptoms).
- Alternatively, it can be given (or re-offered) a little later, after it has been decided that some procedure (CEA/CAS) should be recommended.
- Likewise, the leaflet can be given either before detailed arterial investigation (by MRA or CTA) has checked whether CEA or CAS are both anatomically practicable, or it can be given (or re-offered) afterwards.
- **Please check** that the name of a local ACST collaborator has been written onto the middle of the consent form (page 7 of this leaflet) before giving the leaflet.