# **PATIENT INFORMATION SHEET**

**The European Carotid Surgery Trial-2 (ECST-2)**

**ISRCTN97744893**

You are invited to participate in a research project we are running to compare the risks and benefits of two treatments for carotid artery narrowing. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**What is the purpose of the study?** Narrowing of one of the carotid arteries in the neck, which supply blood to the brain, is an important cause of stroke. It is therefore important to give treatment to prevent the narrowing causing a stroke. The traditional method of treatment is a surgical operation (endarterectomy), often performed under a general anaesthetic, in which the diseased part of the artery is cut out through an incision in the neck. More recently carotid artery stenting has been used as an alternative to endarterectomy. Stenting involves placing a small tube made of wire mesh, called a stent, in the artery in the neck through a small tube (catheter) inserted in the groin under local anaesthetic. Once in position across the narrowing the stent is opened out where it acts like a spring to keep the artery open. Surgery and stenting both carry a small risk of causing stroke at the time of treatment. However, modern medical drug therapy may be as effective as endarterectomy or stenting in suitable patients at preventing stroke from carotid narrowing, especially if the medications are adjusted to get the best effects. We call this “optimised medical therapy” or “OMT”. If we can show that OMT is as effective as surgery or stenting, in the future patients will be able to avoid having early surgery or stenting, avoiding the risks of these treatments. However, we need to confirm our proposal that OMT is as good as surgery by comparing the progress of patients treated by OMT alone, or combined with either surgery or stenting.

**Why I have I been chosen?** You have been chosen because the tests that you have had revealed that you have carotid narrowing that may benefit equally from either optimized medical therapy (OMT) alone or combined with surgery or stenting.

**Do I have to take part?** Your participation in the trial is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

**What will happen to me if I take part?** To find out which treatment is better, half the patients entering the study will be allocated to be treated as soon as possible with surgery or stenting (your doctor will decide with you before allocation if you will get surgery or stenting) and OMT. The other half of the patients will be allocated to be treated by OMT alone and surgery or stenting will be postponed until such time, if ever, it becomes clearly necessary. The treatment is allocated by a computer, which chooses the treatment for each individual by chance. This will allow us to compare the benefits and risks of the two treatments fairly. If you agree to join the study your GP will be informed and you will be seen by a neurologist or stroke physician or an assistant under their supervision approximately 30 days after your treatment, after six months and then annually after entering the study for up to 10 years. You will also have an MRI brain scan done before or soon after you join the study unless you are not able to be scanned using MRI or unable to tolerate MRI. If you cannot have an MRI, you will have a CT brain scan instead. You may also have an additional MRI scan and ultrasound scan (a non-invasive sound picture of the arteries which does not use radiation) of your carotid arteries to image the fatty deposits narrowing your artery. The MRI brain scan will be repeated around one month after your treatment and then again 2 and 5 years later. The brain scans will allow us to accurately measure whether you have any pre-existing damage from the carotid narrowing or other conditions, and will allow us to monitor your progress and find out if you develop any new brain damage. The carotid artery scans will allow us to determine the characteristics of your carotid narrowing which might help us in the future predict who needs their narrowing removed and who will do as well with OMT alone. MRI is very safe and used widely in medicine, but cannot be used if you have large bits of metal in your body or a cardiac pacemaker, or if you are very claustrophobic. CT scanning involves the use of X-rays. Women who are or might be pregnant *must*inform a member of staff in advance. The amount of radiation used is more than an ordinary X-ray of the chest or body and is equal to the natural radiation that we receive from the atmosphere over a period of approximately three years. A carotid ultrasound and/or MRI or CT of the arteries will also be performed when you join the study to measure the severity of the stenosis and then an ultrasound will be performed one month to six weeks later and repeated at intervals during follow up to assess the success of treatment. You will be asked to fill in a questionnaire about your health and how you feel about yourself before your allocated treatment and at follow-up visits. You will also be asked to take a quick test to assess your memory and other cognitive skills. You may also be telephoned at home by a member of the research team to see how you are doing in between visits to the hospital.

**What will happen if I am allocated optimized medical treatment (OMT) alone?** If you are not already receiving it, you will be prescribed medications to prevent blood clotting, lower blood pressure and blood cholesterol levels in accordance with current best medical practice. You will be monitored to see that target levels for blood pressure and blood cholesterol levels are reached. You will also be advised about smoking cessation and reduction of body weight, if required.

**What will happen if I am allocated surgery?** You will be scheduled to have surgery as soon as routinely possible and the operation will be performed by an experienced surgical team. You may need to have a general anaesthetic to put you to sleep during the operation. After the surgery you will be seen by a member of the team to check how you are doing. You will also have a small blood sample taken and a recording of your heart (ECG) made to check that you have not suffered a heart attack. Once you have recovered from surgery you will be placed on the OMT regime.

**What will happen if I am allocated carotid stenting?** You will have a fine wire and tube inserted into an artery in the groin, which will be used to feed the stent up the artery and into the neck, so that it can be placed across the narrowing in the carotid artery. This is normally done following a local anaesthetic injection into the groin area, but you will stay awake during the procedure. A balloon or filter device may also be fed up the artery to collect any debris that may be dislodged during the stenting procedure. X ray pictures (angiography) will be taken immediately before, during and after stenting the artery to make sure the wire and stent are in the correct place. After the stenting you will be seen by a member of the team to check how you are doing. You will also have a small blood sample taken and a recording of your heart (ECG) made to check that you have not suffered a heart attack. Once you have recovered from stenting you will be placed on the OMT regime.

**What are the possible disadvantages and risks of taking part?** Both surgical endarterectomy and stenting carry a risk of causing a stroke at the time of the treatment. Previous trials showed a risk of stroke or death at the time of surgery or stenting of between 3 and 6 patients in every 100 patients. Treatment is not always successful and the narrowing may recur and require further treatment or the artery may become blocked. A proportion of people treated with OMT alone will also suffer stroke at some time during follow up despite treatment. Stroke caused by surgery, stenting or occurring during OMT may recover, cause permanent disablement or be fatal. However, you are being considered for the study because the risks of strokes following surgical or stenting treatment with OMT are believed to be similar to those on OMT alone.

**What are the other main risks of surgery?** Surgery also has a risk of causing a heart attack. About one in ten patients has temporary tongue or facial weakness. A large blood clot (haematoma) may form at the site of incision, which may require removal. Surgery results in a permanent scar in the neck.

**What are the other main risks of stenting?** Angiography and stenting may also result in bruising or haematoma at the site of injection (usually in the groin) and can cause temporary discomfort or pain in the neck. There is a small risk of allergic reactions to the dye.

**What are the other main risks of OMT?** The drugs used as part of OMT may cause adverse reactions or allergic reactions.

**Collection of blood and tissue samples.** If you receive surgery as part of your treatment in the trial, the tissue removed from your carotid artery will be kept and examined to provide information about the structure of the narrowing which we can compare with information we obtain from other techniques to assess the degree of narrowing in the artery and the risk it poses and use it as a check on them. In addition to blood samples taken for routine diagnostic tests we will keep a sample of your blood to use for genetic analysis to find out if there are any genetic factors predicting the risk of the type of problem you are being treated for. Samples may also be used to look for evidence of infection or inflammation as a cause of stroke.

**The risks of blood sampling.** These are slight but include: excessive bleeding, fainting or feeling light-headed, haematoma and infection (a slight risk any time the skin is broken), these will be minimised by the collection being carried out by experienced, trained individuals using appropriate techniques.

**What are the possible benefits of taking part?** All patients taking part in the trial will receive careful follow-up and the opportunity to benefit from advances in treatment. Overall, treating carotid narrowing and optimizing your medical therapy will reduce your chances of subsequent strokes.

**What will happen if I loose the capacity to consent during the trial?** An importantpart of this trial is to determine if the treatments have any influence on changes in your mental capacity that may be caused by your illness. Therefore it is important that we are able to continue to collect data about you if for any reason you become unable to consent during the course of the trial. You will continue to be followed up in the trial unless in the opinion of your medical team or carer(s) you are finding it distressing to do so, in which case you will be withdrawn from further follow up. Follow up in this case will consist of assessment by the medical team at the hospital if transport to and from the appointment can be arranged for you without causing distress, alternatively the medical team may contact your carer or general practitioner by telephone to get information regarding your condition. Data collected about you up until the time of your withdrawal will be retained and used in the analysis of the results, subject to the measures to maintain confidentiality outlined below.

**What if something goes wrong?** Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

If you suspect that the injury is the result of the Sponsor’s (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to the Professor Martin Brown who is the Chief Investigator for the research and is based at the National Hospital, Queen Square, London WC1N 3BG (Box 6). The Chief Investigator will then pass the claim to the Sponsor’s Insurers, via the Sponsor’s office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the research, the normal National Health Service complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. Details can also be obtained from the Department of Health website: <http://www.dh.gov.uk>.

**Will my taking part in this study be kept confidential?** Your General Practitioner will be informed that you are taking part in the study and advised about the optimized medical therapy (OMT) you will be prescribed for the study.

Information relevant to your medical condition will be collected as part of the study. Information about yourself and your treatment will be kept in the central study office in the Institute of Neurology, University College London, England for analysis. Professor Martin M Brown, the Chief Investigator, will be responsible for the security and access to the information. All information regarding your medical records will be treated as strictly confidential and will only be used for medical research on the factors that influence the diagnosis of or outcome from stroke. The data may be used for future research on stroke by other research institutions in the UK but again your confidence will be strictly maintained. Your medical records may be inspected by competent authorities and properly authorised persons. If any information is released outside the trial office this will be done so in coded form with your name removed from the records so that your confidentiality is strictly maintained. The results of the study will be published in medical journals or other public sites. Information regarding the study will be stored on a secured computer database for a minimum of 20 years.

**Who is organizing and funding the study?** Details of the study organizers and funders can be found on the trial website: www.ecst2.com. University College London is the trial sponsor.

**Who has reviewed the study?** The Cambridge Central Multi-Centre Research Ethics Committee reviewed this study.

Thank you for taking time to consider participating in this study. If you agree to take part, you will be given a copy of this information sheet and a copy of the signed consent form.

**Further information can be obtained from**:

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