International Carotid Stenting Study (ICSS)

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 remove this narrowing to prevent 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. We are studying a new treatment in which is a small tube made of wire mesh, called a stent, is placed inside the narrowed artery in the neck. The stent is placed into the artery through a small tube (catheter) inserted in the groin under local anaesthetic. Injections of dye will be made through the catheter to take Xray pictures of the narrowing. This is called angiography. Once in position across the narrowing the stent is opened out where it acts like a spring to keep the artery open. This new treatment is known as carotid artery stenting. Stenting has been used successfully in the arteries supplying the heart and the legs. Stenting avoids the discomforts of surgery and risks of general anaesthesia but we do not know which treatment is better overall for the patient.

Why I have I been chosen? You have been chosen because the tests that you have had reveal you may benefit from either surgery or the insertion of a stent.

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 with surgery and the other half to be treated by stenting. 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. All patients entering the study will receive the best possible medical treatment, including aspirin or similar tablets, if tolerated, and careful treatment of high blood pressure or raised blood fats. If you agree to join the study your GP will be informed and you will be seen by a neurologist approximately 30 days after your treatment, after six months and then annually after entering the study for up to 5 years. At each visit a carotid ultrasound (a non-invasive sound picture of the arteries which does not use radiation) will be performed to assess the degree of narrowing. 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.

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. An angiogram may be performed before or after the procedure. You will usually have to stay in hospital for several days after surgery.

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 taken immediately before, during and after stenting the artery to make sure the wire and stent are in the correct place. In a small percentage of patients, the angiography may show that stenting is not possible. In this case, you will be referred for surgery instead. If you are well after the stenting procedure you will be able to go home the day afterwards.

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 significant risk of stroke or death at the time of surgery or stenting of between 6 and 10 in every 100 patients. There is a small risk of about one in a hundred that angiography will cause a stroke. Stroke caused by

surgery, stenting or angiography may recover, cause permanent disablement or be fatal. However, you are being considered for the study because the risks of strokes resulting from surgical or stenting treatment are believed to be less than leaving the carotid artery narrowing untreated. Treatment is not always successful and the narrowing may recur and require further treatment or the artery may become blocked.

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 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 will reduce your chances of subsequent strokes.

What if something goes wrong? If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for taking legal action but you may have to pay the legal costs. Regardless of this, if you wish to complain, or have any concerns about this study, the normal National Health Service complaints mechanism should be available to you.

Will my taking part in this study be kept confidential? Information relevant to your medical condition will be collected as part of the study. Medical 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 Principal 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, but 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 15 years.

Who is organizing and funding the study? The study is organized by the Stroke Research Unit at the Institute of Neurology, UCL and funded by grants from The Stroke Association, Sanofi Synthelabo and the European Union.

Who has reviewed the study? The NorthWest 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:

[redacted]