PATIENT INFORMATION SHEET

Vertebral artery Ischaemia Stenting Trial (VIST)

*You are invited to participate in a **RESEARCH** project we are running to compare the risks and benefits of a new treatment called stenting for narrowing of the vertebral artery supplying the brain. Before you decide whether to take part it is important that you understand why the research is being done and what it will involve. Please take time to read the following information sheet carefully and discuss it with friends, relatives, and your GP if you wish. Do ask us if there is anything that is not clear to you or if you would like more information.*

Consumers for Ethics (CERES) publish a leaflet entitled "Medical Research and You". This leaflet gives more information about medical research and looks at some questions you may want to ask. A copy may be obtained from CERES, PO Box 1365, London N16 0BW.

1. What is the purpose of the study? Narrowing (stenosis) of the vertebral and basilar arteries in the neck, which supply blood to the back of the brain, is an important cause of stroke. Patients with stroke due to vertebral and basilar artery stenosis have an increased risk of further stroke. We can now treat vertebral stenosis with a stent. This involves placing a small tube made of wire mesh inside the narrowed artery in the neck. The stent is passed into the artery through a small tube (catheter) inserted into 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. Stenting has been successfully used in artery supplying the heart and the legs and it is now a routine treatment for these diseases. It has also been used in many cases of narrowing of the arteries at the front of the brain (carotid arteries). Hundreds of cases of vertebral stenosis have been treated by stents world-wide but we don't yet have any information as to whether it is better to perform stenting or to treat with drugs alone. Therefore in this study, which will be carried out in many different hospitals, we are comparing whether stenting is better than standard drug treatment alone in patients who have had recent stroke due to vertebral stenosis.

2. Why have I been chosen? You have been chosen because you have had a recent stroke and also have vertebral stenosis.

3. Do I have to take part? Your participation in the study 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 without giving a reason. If you decide not to take part in the study the standard of care you receive will not be affected.

4. What will happen to me if I take part? To find out which treatment is better, half of the patients entering the study will be allocated to treatment by stenting and the other half will be treated with standard drug treatment alone. Which treatment you are allocated to will be decided by a computer. This random allocation is important if we are to determine fairly which of the two treatments is better. All patients entering

the study will receive the best possible medical treatment including aspirin or similar tablets and treatment of risk factors such as high blood pressure and cholesterol. If you agree to take part your GP will be informed and you will be seen by a neurologist or stroke doctor about one month after your allocated treatment, and at one year. We will also contact you by telephone at 6 months and yearly from year 2 onward until end of study. At one year we will perform a further MRI or CT scan to determine the degree of narrowing in the artery. You will be asked to fill in a diary recording contact with Health Services. Any travel expenses incurred from the visits of this study will be reimbursed.

5. What will happen if I am allocated stenting? Stenting will be carried out by an experienced radiologist. He/she will insert a fine wire and tube into an artery in the groin (or occasionally the arm) and this will be used to feed the stent through the blood vessels into the neck. It will be placed across the narrowing in the vertebral artery. This is usually done following a local anaesthetic injection into the groin but you will stay awake during the procedure. Balloons may also be used to dilate the artery before inserting the stent. Sometimes, if the radiologist feels this is a better treatment, the narrowing will be treated by the balloon alone (angioplasty) without insertion of a stent. X-ray pictures (angiography) will be taken immediately before, during, and after stenting to make sure that the wire and stent are in the correct place. In occasional patients the angiography may show that stenting is not possible, or that the degree of narrowing is not as bad as we thought and therefore stenting is not necessary. If this is the case you will be treated with best medical therapy alone.

6. What are the possible disadvantages and risks of taking part? Stenting carries a risk of causing a stroke at the time of treatment. Previous studies have suggested this is about five per every hundred patients. There is also a risk of about one in every hundred that angiography will cause stroke. On the other hand, if we do not treat the stenosis there is a risk of having a further stroke. We are not sure whether the risk of stenting is greater than the risk if we do not perform the stenting, and that is why we are carrying out the study.

7. What are the other main risks of stenting? Angiography and stenting may also result in bruising at the site of the introduction of the stent (usually the groin). There can be temporary pain or discomfort in the neck when the balloon is blown up. If you receive stenting then X rays are required to allow us to ensure that the stent is placed in the correct position and this does involve a small radiation dose which may carry a small risk of induced cancer (1 in 1300).

8. What are the possible benefits of taking part? All patients taking part in the study will receive careful follow-up and the opportunity to benefit from advances in treatment.

9. What if something goes wrong?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of the study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the Patient Advice and Liaison Service (PALS) (email: pals@addenbrookes.nhs.uk, tel: 01223 216756) at Addenbrooke's Hospital, Hills Road, Cambridge CB2 0QQ. There are no special compensation arrangements unless this was due to the negligence of one of the doctors or nurses or due to harm resulting from the study design. In this case you may have grounds for legal action for compensation but you may have to pay your legal costs. The normal hospital complaints mechanism will still be available to you. In addition, any harm arising due to study design (both negligent and non-negligent) will be covered under the Sponsor's insurance policy.

10. Will my taking part in this study be kept confidential? Information relevant to your medical condition will be collected as part of the study. This information will be kept in the study office at St George's University of London. Your details will be passed to the NHS Information Centre and the NHS Central

Register to assist us in keeping in touch with you and to keep track of your health status. If we do lose contact with you the NHS Information Centre will provide the VIST central office with details of the Primary Care Trust (PCT) that you are registered with. The VIST Central Office will then write to the PCT to request details of your General Practitioner (GP), the Chief Investigator will then write to your GP to ask for your contact details so he can contact you via telephone or in writing. All information regarding your medical records will be treated as strictly confidential and will only be used for medical research. 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 study office this will be done so in a coded form with your name removed from the records so that your confidentiality is strictly maintained. The results of this study will be stored on a secured computer database for a minimum of ten years.

11. Who is organising and funding the study? The initial phase of the study has been funded by the Stroke Association and will now follow in to a full, definitive phase funded by the NIHR Health Technology Assessment Programme. The study has been reviewed by a number of experts selected by the Stroke Association and the NIHR HTA Programme. This study is being co-ordinated from St George's, University of London and the University of Cambridge.

Thank you for taking time to consider participating in the 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:

<< Insert Local PI and/or Local Study Coordinator name and contact details>>

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