PATIENT INFORMATION SHEET

Local Investigators: ……..

ENOS – Efficacy of Nitric Oxide in Stroke

You are being invited to take part in a research study. 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. Talk to others about the study if you wish. Ask us if there is anything that is not clear to you, or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

Lowering blood pressure reduces the risk of further strokes in patients who have already had one or more strokes. High blood pressure is common in the first hours and days following a stroke and increases the risk of the patient not recovering fully and being left with some disability. Lowering blood pressure in the first hours and days after stroke with medications might help patients to recover. Although at present we routinely treat high blood pressure long term after a stroke, we do not do so immediately after the stroke.

We aim to assess in a trial what effect glyceryl trinitrate (or GTN) has on how well people recover from strokes. GTN is a tried and tested drug in other medical conditions that acts quickly to relax blood vessels and lowers blood pressure. The data will help doctors decide whether blood pressure lowering treatments like GTN can be used in patients with acute strokes to try and improve recovery.

Why have I been chosen?

You have been chosen because you have had a stroke and are over the age of 18 and because your blood pressure is high.

Do I have to take part?

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. You are still free to withdraw at any time and without giving a reason.

Deciding to withdraw from the study will not affect the standard of care you receive.

What will happen to me if I take part?

Your involvement in the study will last for 3 months. If you decide to take part in this study the study doctor or nurse will ask you about your medical history and take your blood pressure.

In this study GTN is given in a patch much like the patches people use to stop smoking. A computer will decide at random whether you will receive the treatment patch or nothing. We are doing this because we don't know which way of treating patients is best. To find out, we need to make a comparison between GTN or no GTN. We put people into groups and give each group a different treatment and the results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). In this study half the patients will receive the active patch and half will have no patch.

Once you have been assigned a treatment, the nurse will come and put a dressing on your arm or chest. You will not know if there is a treatment patch under the dressing or not, but the nurses and doctors will know. This will need to be changed once a day for 7 days, and then the treatment will stop.

The second part of the study is only for patients already taking treatment for high blood pressure. It involves either having your usual blood pressure medicines stopped for 1 week or continued as usual. If the treatment is stopped, it may be restarted after one week depending on your doctor's wishes.

If you have had a routine CT brain scan before entering the trial then we may repeat the head CT scan at day 7. If you have not had a CT brain scan before entering the trial then you will only have a routine scan as normal.

During the next 7 days a doctor will check your condition looking in particular for signs of side effects of the treatment.

You will be contacted 3 months after your stroke for a short talk on the telephone (or by post) by a member of the research team. This is to check your condition at that time. In order to make the final evaluation of the study as objective as possible, the person who telephones you will not know if you received the active treatment or not.

A small amount of blood (about an egg cup full) may be taken by a local researcher at the start of the trial, and again at day 7, and then stored. This will be used for two purposes. Firstly, we will see if variations in your genetic code are related to your stroke and if the effect of GTN on blood pressure is altered by some of your genes. Secondly we will see if GTN alters the levels of certain blood substances. After the blood has been tested the sample will be destroyed. You will not be able to see the results of these tests.

You may also need an ultrasound scan (sound wave test) of your neck. This is not painful or harmful. In most cases this will be as part of the routine investigations that stroke patients usually receive.

Other than described here, your treatment will be exactly the same as for all stroke patients.

Expenses and payments
Volunteers will not receive payment for participating in this study. There will be no charge for the trial medication.

What is the drug, device or procedure that is being tested?
GTN is a medicine which has been used for many years to treat heart problems. It is not used as a long-term blood pressure medicine but does lower blood pressure quickly and effectively for short periods in patients with a stroke and that is why we are using it in this study.

What are the alternatives for diagnosis or treatment?
There are various licensed medications used to lower blood pressure sometime after a stroke. You do not need to take part in this study to receive blood pressure treatment. You should discuss the options with your doctor before deciding whether to take part in the study.

If you decide to take part in the study, this will not affect your right to receive appropriate medical care from your doctor.

What are the side effects of any treatment received when taking part?
All drugs have the possibility of side effects. The side effects from GTN are generally mild. They can include headache, low blood pressure and dizziness.

You must inform your GP or member of the research team if you feel you have had a reaction to the medication.

What are the other possible disadvantages and risks of taking part?
You will need to be followed up by the research team for 3 months after starting the study. The study may involve an additional CT scan which involves the use of x-rays, although the amount of x-rays you would be exposed to would be small and is of low risk.

You may have an extra blood sample taken which may cause some discomfort. This can occasionally lead to bruising or bleeding at the site shortly after the blood is taken.

What are the possible benefits of taking part?
Your participation in this study may reduce the symptoms of your stroke or improve your long-term recovery. However, we cannot promise the study will help you, and your participation is voluntary. The information we get from your involvement may benefit other people who may have a stroke in the future.

What happens when the research study stops?
We aim to treat 5,000 patients in this study. When it has finished we will look at the data and decide if this is a useful treatment for stroke. We will not directly tell you the results of the study, but they will be published in a journal where they can be read.

Will my taking part in the study be kept confidential?
If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons organising the research.

They may also be looked at by representatives of regulatory authorities and by authorised people from the Trust, or other NHS bodies to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site.

Your contact details, and those of a relative or friend that you provided, will be passed to the International Coordinating Centre in Nottingham and the National Coordinating Centre in your country. This will enable the three month telephone follow up to take place.

Scan data, which has been made anonymous, may be shared with allied research projects and used for education and research.

The National Coordinating Centres may use central databases to obtain additional follow-up information on patients enrolled into the trial. In the UK, this will involve use of the NHS Medical Research Information Service, Office of National Statistics.

Our procedures for handling, processing, storage and destruction of patient's data are compliant with the Data Protection Act 1998.

Contact Details:
If you have any questions or concerns do not hesitate to contact the research team on……..

What if relevant new information becomes available?
Sometimes during the course of a research project new information becomes available about the treatment/drug that is being studied. If this happens, your research doctor will tell you about it and discuss whether you want to or should continue in the study, although after the first 7 days you will no longer be receiving GTN. If you decide not to carry on, your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. They will explain the reasons and arrange for your care to continue.

If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

What will happen if I don't want to carry on with the study?
If you withdraw from the study, we will destroy all your identifiable samples, but we would like to use the data collected up to your withdrawal.

What if there is a problem?
If you had a reaction to the medication we would stop the medication and appropriate medical care would be given. Any adverse events are monitored.

Complaints
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions on……..... If you remain unhappy and wish to complain formally, you can do this through the formal complaints procedure.

Harm
If you are harmed during the research and this *is* due to someone's negligence then you may have grounds for legal action for compensation, but you may have to pay your legal costs. The normal hospital complaints mechanisms will be available to you.

If you are harmed during the research and this is *not* due to someone's negligence then there are no special compensation arrangements, but you may still follow the normal hospital complaints mechanisms. Again you may have to pay your legal costs.

The University of Nottingham maintains Clinical Trials Insurance to cover the University's legal liability.

Involvement of the General Practitioner/Family doctor (GP)
If you are enrolled in the study we will inform your General Practitioner as a matter of courtesy.

What will happen to the results of the research study?
The results of the research may be published. If so, this will be in a medical journal. You will not be identified in any report.

Who is organising and funding the research?
This study has been funded by Medical Research Council (MRC). The University of Nottingham is sponsor for the study.

Who has reviewed the study?

Both a national multicentre and local research ethics committee have reviewed the research.

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