St George's University of London

St George's Healthcare NHS
NHS Trust

**PATIENT INFORMATION SHEET**
**CADISS (Cervical Artery Dissection in Stroke Study)**

**Introduction**
You are being asked as a patient to join in a research study and before you decide it is important you understand what the research is all about. We suggest you read this with other members of your family and direct any questions to the physician in charge of your case. You should not give your consent until you are sure you fully understand the study

**Why are we doing this study?**
1) Your stroke is due to tearing (dissection) of one of the arteries in your neck which has released blood clots to your brain. Although the chances are low that further episodes will occur, it is standard practice to give a blood thinner for the next 6-12 months to prevent such further episodes

2) One of two drugs is always given. All study patients receive either antiplatelets (such as aspirin) or anticoagulants (such as warfarin). No one knows at present which is better. Aspirin is safer but may be less effective, while warfarin is possibly stronger but has the slight danger of bleeding.

3) The plan is to allocate at random one of these two drugs to all consenting patients. Both the patient and your hospital physician will know what drug you are taking, but the principal investigators at St Georges Hospital, London will not.
Each patient will participate for one year. You will be followed up medically at intervals over this time, either by phone or personally, to document your progress.

**Why were you chosen?**
There are 27 hospitals participating in this study throughout the UK, and we anticipate that each hospital will admit about 10 patients per year with stroke due to dissection, so over the 2 year study we expect to enrol about 500 patients

**Do I have to take part?**
We should emphasise that this is an entirely voluntary study and if you would rather not participate you will be treated in the usual way your physician thinks best. There are no personal disadvantages by deciding against joining.
If you decide to join, you will be asked to sign a consent form, but you can withdraw from the study at any time. This would not affect the continuing care you will get.

**What will happen if I decide to take part?**
The study will not delay your hospital discharge. You will continue to take the allocated treatment for up to 6 months as an outpatient, and be followed approximately at 3 month intervals, either personally or by phone. Your supervising physician will be in charge of your case. All your hospital data will be confidential and coded and your name will not appear on any research documents. You and your hospital doctor will know what treatment you are on, as will your GP.

At the end of the study, approximately 2 years, we will analyse the data of all 270 patients to determine the better of the two treatments. This will prove of great value to future patients, whatever the outcome. In your case the result is unlikely to affect your care since

in most cases you would stop aspirin or anticoagulants any way. This study will not affect your lifestyle, except those restrictions which apply to anyone taking these drugs under normal circumstances.

**What if new information becomes available during the study?**
Should new treatment such as alternative drugs become available while you are in the study, your hospital doctor will discuss with you whether you should take this other treatment

**Complications of the drugs**
Both drugs may produce (usually minor but rarely, serious) bleeding in the skin or gums, or sometimes from the stomach, and in most cases stopping treatment usually solves the problem.

Anti coagulants (warfarin) are more likely to cause bleeding than aspirin, but these drugs are commonly used by doctors for a variety of other disorders such as heart attacks, and if monitored by periodic blood tests this complication is seen in less than 1% of patients
However, if you are harmed by these complications no special compensation is available other than would occur during the course of treatment under non research circumstances. If it is due to negligence, then all the usual legal recourses will be open to you, including the normal NHS complaints mechanisms

**Outcome of the study**
During the study we will be presenting interim results at various medical meetings. No patient identification will be revealed and the results will be presented as a whole population of study patients
At the end of the study, approximately two years, we will analyse the data of all patients to see if one treatment is superior. This data will be published in a medical journal.

**Contact for further information**
Should you need more information, please contact your hospital physician in charge of your case: _____

**Additional study – TCD**
We plan to perform a monitoring study in some patients. This is an ultrasound scan which can be used to measure blood flow in the brain. It is called TCD (Trans Cranial Doppler). A probe is placed on either side of your head. There is no discomfort and no hazard. The scan can detect very small blood clots passing through the brain and therefore may give us an indication of how effective the treatment is. We would perform a one hour recording before you start your study treatment and another one hour recording one week later. If you prefer not to have it, it will not affect your participation in the main study in any way.

**Follow up of ineligible patients**
If you are not suitable for the study or do not wish to take part we are still keen to follow your progress. In these circumstances, you will not be allocated at random to a drug treatment but your doctor will discuss with you which treatment would be best for you. This information is important because it will let us know whether the results of the study are likely to apply to all patients with dissection. If you agree to this we would collect details about your dissection both at the time of the dissection and at 3 months follow-up.

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