For Trial Participants

Please note that the ASTRAL trial and its associated sub-studies closed to recruitment in October 2007.

Considering taking part? Find out more about the trial:

The ASTRAL Study

You are being invited to take part in a large national research study, called ASTRAL, of the treatment of atherosclerotic renovascular disease (ARVD). This leaflet provides information about the study. If you choose not to take part in the ASTRAL study, you do not have to give a reason and your future standard of care will not be affected.

What is ARVD?

Blood is supplied to your kidneys by the renal arteries. In ARVD, one or more of these arteries becomes narrowed or blocked and, if a kidney does not receive the oxygen it needs, it may not work properly. Blood pressure may also rise and this may be harmful. If left untreated, an affected kidney may stop working altogether.

How can narrowed arteries be widened?

There are two methods (collectively known as “revascularisation”) that are designed to achieve opening of the arteries. The first method is called “balloon angioplasty” and involves inserting a thin tube with a deflated balloon at the tip into the artery in your leg. This is guided to your kidney artery by X-ray. The doctor then inflates the balloon inside your artery to widen the artery. The second method is called “stenting”, in which a tiny metal tube (called a stent) is inserted into the artery, in much the same way as balloon angioplasty is done, to help prevent the artery narrowing again. Often both angioplasty and stent insertion will be done, though sometimes either just angioplasty or, more rarely, just stent insertion will be carried out.

Does revascularisation work?

Revascularisation can usually successfully widen the artery. Although there is a chance that the artery will narrow again, the procedure can often be repeated if this does happen. However, as with all such procedures, there is a small risk of complications during and after the procedure.

What are the risks of revascularisation?

Although balloon angioplasty and stenting are generally safe procedures, complications can occur. These are usually minor, such as bruising at the groin, but occasionally they can be more serious and cause permanent damage to the kidney. Very rarely, perhaps in about one case in every hundred, surgery may be necessary to correct the damage.

If these procedures are available, why do we need a clinical trial?

Although both balloon angioplasty and stenting can widen the artery, doctors are uncertain whether these procedures actually help the kidney work better and are of long-term benefit to patients such as you. Previous studies have been small and have not provided reliable evidence to help doctors decide how best to treat you. For this reason, we would like to ask you to help us find out whether or not these treatments are helpful.

Which patients will get angioplasty and stents?

Your doctors will discuss with you the treatment options available. If your doctors feel sure that you should have an angioplasty and/or stent, you will not be asked to take part in this research. Similarly, if your doctors feel sure that you should not have these treatments, again you will not be asked to take part. Only if your doctors are uncertain as to the best treatment for you will you be invited to take part. If you do agree to enter the ASTRAL study, the treatment you get will be decided at random with the assistance of a computer (similar to tossing a coin). Half the patients will have revascularisation (generally with either angioplasty alone or both angioplasty and stenting) and the other half will not. Neither you nor your doctors will be able to choose your initial treatment (unless your circumstances change unexpectedly, in which case your doctors will be free to recommend the treatment that they feel is best for you).

What does the ASTRAL Study involve?

If you do choose to enter the ASTRAL study, your doctors will send basic information about you and your condition to the study’s central organisers at the University of Birmingham Clinical Trials Unit to allow the results to be analysed. Your GP will also be informed that you are in the study. In addition to the hospital staff, someone from the central study office may review your hospital notes. All information about you will be kept securely and in strict confidence. No information that will identify you as an individual will be published in the trial report.

Whether or not you have revascularisation, you will be asked to come back to the hospital for a check up about one to three months later, and also six to eight months later. A blood sample will be taken, so that we can check how well your kidney is working, and any drugs you are taking will be reviewed. After that, we would like you to

provide a blood sample at yearly intervals for up to five years in order to monitor your long-term progress. In some centres, patients will be asked to undergo a repeat angiogram after one year to check the width of the artery to the kidney. Your doctors will tell you before you agree to take part in the study if they would like you to be one of these patients. Other than this, participating in the trial requires no additional tests or visits to hospital other than those that would normally be needed as part of your standard medical treatment.

Do I have to take part in the study?

No, you do not have to take part in the ASTRAL study, or give a reason if you choose not to. Before deciding, you should read this information carefully and ask your doctors if there are things you do not understand. If you do decide to take part, we will ask you to sign a consent form indicating that you understand what the study involves and agree to take part.

Will participation affect my legal rights?

There are no special arrangements for compensation in the (unlikely) event of you being harmed as a result of taking part in the ASTRAL study. But, whether or not you do take part, you will retain the same legal rights as any other patient treated in the National Health Service.

Can I withdraw from the study if I change my mind?

Yes, you can decide to withdraw from the study at any time. Signing the consent form does not commit you to receiving the revascularisation (if allocated), or being denied revascularisation should you subsequently require it. If you change your mind later, you do not have to give a reason and withdrawal from the study will not prevent you from receiving the treatment that your doctors consider best for you.

Do you have any other questions?

If, having read this information, you still have any questions, now or later, please feel free to ask your hospital doctors or nurses, or your GP. If you would prefer to delay your decision, perhaps to discuss things with relatives or friends, then you can make an appointment to come back later. Please keep this information sheet in a safe place and you may want to write the names and telephone numbers in your diary or address book.

Thank you for taking the time to consider participating in this study.