Renal Denervation – Patient information

You have been invited to have a procedure called renal artery denervation. This is a new procedure for the treatment of patients with high blood pressure that is difficult to control (resistant hypertension). Several studies have showed that this treatment can be very effective at controlling very high blood pressure. Studies into the current technique for renal artery denervation have been on-going in humans for more than five years and so far no serious side-effects to the procedure have been reported. However, we currently do not have any information on the longer-term effects of this treatment.

It is important to fully understand the implications of any procedure you are planning to undertake and for this reason we recommend you spend some time reading this information leaflet carefully.

Why have you been invited to have renal artery denervation?
You have very high blood pressure despite taking a powerful combination of blood pressure lowering tablets. This high blood pressure is putting you at an increased risk of suffering a stroke or heart attack.

The doctors involved in your care think that you may benefit from renal denervation. So far the patients who seem to benefit the most are those with a systolic (the first number in the blood pressure reading) blood pressure greater than 160mmHg despite treatment with three or more medications.

What is the background to this procedure?
High blood pressure is one of the most common and preventable causes of premature heart disease, kidney disease and stroke in the UK. About 1 in 4 adults and more than half of those over the age of 60 are affected.

The cause of the majority of cases of high blood pressure is not fully understood and is generally described as ‘essential hypertension’. A number of different factors are known to be important, including an increase in salt retention and a reduction in kidney blood flow partly affected by nerves involved in ‘stress’ responses (the sympathetic nervous system).

What is standard treatment for high blood pressure?
The standard treatment for high blood pressure in the United Kingdom is a combination of drugs with lifestyle changes such as reducing salt in the diet, increasing exercise and losing weight where appropriate.

Despite treatment, about half the patients taking medication for high blood pressure will continue to have high blood pressure. There are a number of possible reasons for this, which include:

1. Inadequate drug treatment: not being given adequate doses or appropriate combinations of medication
2. Not taking the tablets regularly or in the amounts suggested by your doctor
3. Other rare causes of high blood pressure, so called secondary hypertension

Before having the renal denervation procedure done, we will have a discussion with you and carry out various investigations to make sure none of these reasons apply to you. If you have any problems with taking your tablets regularly please let us know so we can make sure you are getting the right treatment.

Renal artery denervation has been shown to be effective at lowering blood pressure in two medical trials in appropriately selected patients and a third trial is currently under way. Whether this treatment is appropriate for all patients is not clear. It may also have other benefits, such as in blood sugar control in diabetics and in heart muscle function in patients with heart failure. Research in these areas is on-going.

Renal denervation will not allow you to stop taking drugs to lower your blood pressure; you will almost certainly need to continue taking your current drug treatment after the procedure.

The National Institute for Health and Clinical Excellence (also known as NICE), the body that advises doctors on treatments in England and Wales, has recommended that where renal artery denervation is carried out as a
treatment for high blood pressure, the results should be collected to assess the safety and effectiveness of the procedure. Before the procedure we will ask for your permission to share some of the information we collect during and after the renal denervation procedure. This will be stored in a national registry and will help us target this technique most effectively in the future. No personal details will be shared with anyone outside the hospital. If you would rather not participate in this process, you can choose not to have your data stored in the National Registry.

What does renal artery denervation involve?

Most people have two kidneys, each of which is supplied with blood through an artery (the renal artery). There are nerves running along the outside of these arteries (the renal sympathetic nerves) which carry signals between the kidney and the brain and control blood pressure. In this procedure we plan to interrupt these nerves which has been shown to lower blood pressure.

It is important to know that kidneys seem to work perfectly well doing their normal job, removing waste products and excess water from the body, without these nerves, as they do in patients with transplanted kidneys. We also know that cutting these nerves can reduce blood pressure but it is not practical to do this as the risks of such a procedure would be too high.

The new method of renal artery denervation uses a special wire fed up inside the artery from one of the blood vessels in the groin. The wire is steered to the wall of the renal artery and high frequency energy is used to heat the area. This heating damages the sympathetic nerves supplying the kidneys in a controlled way which, over several months, is likely to lead to a fall in blood pressure.

The procedure is usually done under local anaesthetic and sedation. This means you will feel drowsy and relaxed but usually not asleep. After injection of local anaesthetic into the skin of your groin over the femoral artery (the main artery to your leg) a tube will be fed into the artery and through this a catheter (fine tube) is advanced into the renal artery under X‐ray control. A dye is injected through the catheter to confirm the position inside the artery. A special wire is then fed through the catheter and high frequency energy delivered to heat the wall of the artery from the inside. The right amount of energy is used to make sure that the artery wall does not get too hot and damage the artery itself. Each of your arteries takes about 15 minutes to treat; the whole procedure takes around an hour.

Pain and pain control.

During the energy bursts to the nerves many patients feel some pain or discomfort in the back or loin area. We will give you some powerful pain killers in advance so that this is manageable and we can give more during the procedure if needed. We will ask you how you are feeling during the treatments to make sure you have enough sedation and pain killers. The pain is a sign that the wire is in the right place, because it comes from the same nerves that we are trying to damage. This discomfort usually passes quite quickly once the treatment has been completed.

Is renal artery denervation safe?

This is a fairly new technique and the information available so far indicates it is very safe. No‐one has died and there has been no documented lasting damage to a kidney. The commonest side effects include bruising at the groin.

Other rare but potentially more serious side effects that have been described are:

1. Damage to the renal artery. One case has been reported and this can usually be dealt with by placing a stent in the damaged artery (like an internal scaffold or spring to keep it open).
2. Persistent abdominal pain lasting beyond the time of the procedure.
3. Low heart rate soon after the procedure which settles with medication.
4. Large drop in blood pressure. This may require you to stay in hospital for a few days to sort out your medication.
5. Damage to the artery in the groin. This occurs about 1% of the time and can require you to need a blood transfusion or rarely a small procedure or operation to the artery.

Other possible side effects that have not been seen with renal denervation, but which can occur after any procedure where an artery is catheterised include an allergic reaction to the x‐ray dye, or the x‐ray dye can damage kidney function.

Potential side effects from renal denervation that have not been seen yet, but might be seen in future, include narrowing of the renal artery, loss of the kidney(s), loss of water and salt control in the body and blood in the urine.

The procedure is carried out using x‐ray guidance, which means you will be exposed to a small amount of radiation. As part of everyday living everyone is exposed to naturally occurring background radiation and receives about 2 millisievert (mSv) each year. The effective dose from the renal artery denervation procedure is approximately 6.5mSv, comparable to that received from many other diagnostic medical x‐ray procedures.
extra radiation therefore represents an additional risk of lifetime fatal cancer of 1 in 3,000. The normal lifetime risk of fatal cancer is currently 1 in 5 so the extra risk with the renal artery denervation procedure is very small.

What steps do I have to go through for the renal denervation procedure?
Your doctor will already have extensively investigated you for other causes of hypertension with a variety of scans and blood tests. These will include tests of the heart and kidneys.

You will require a CT scan or MRI scan of your kidney arteries to make sure you are suitable for this procedure. Prior to your admission your team of doctors will discuss this with you and check that all has been done and that they are in agreement that renal denervation is an appropriate option for you.

Admission to hospital.
Usually you will come in to the hospital ward on the day of the procedure. The procedure will be undertaken by a specially trained doctor. After the procedure, you will be moved to an area where nurses can monitor your recovery. At this time, the sheath in your thigh may be removed and pressure may be applied (sometimes a closure device is used) to the puncture site until any bleeding has stopped. You will be asked to lie flat for several hours and to keep your leg straight to prevent the wound from reopening. Your puncture site will be monitored closely for any signs of bleeding. Should you see any blood or feel warmth at the area of the puncture site, notify your doctor immediately. Your leg will also be monitored for any changes in colour, temperature or sensation. Your doctor will also advise you when you can get out of bed and walk around.

Once you go home, please make sure you remember to take your blood pressure tablets. Your blood pressure will start to fall over several months, not immediately, so it is important you continue to take your regular medication. We will see you in clinic after the procedure to check on your progress and answer any further questions you might have.
Name of Researcher: Dr Piers Clifford

Please initial each box

1. I confirm that I have read and understand the information sheet dated 16 January 2013 (version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to my GP being informed of my participation in the study

5. I agree to take part in the above study.

Name of Patient ___________________________ Date ___________________________ Signature ___________________________

Name of Person taking consent ___________________________ Date ___________________________ Signature ___________________________

Any questions please call: Nicola Bowers Research Sister: 07956645035