

Renal artery denervation (RDN)

Cardiology department

Patient Information Leaflet

You are being invited to have a procedure called renal artery denervation (RDN). Some people have blood pressure that is difficult to control with medication. This may be because those medications are insufficiently effective or have caused side effects. Recent research shows that RDN may be an effective treatment for such people. However, our understanding of long-term effects (beyond about three years) are not known. It is important you spend a few minutes reading this information leaflet carefully and discuss it with others if you wish

Why have I been invited to have renal artery denervation?

You have blood pressure that is elevated above recommend levels either: despite taking a combination of blood pressure lowering tablets that would usually be effective or because you are not able to tolerate usual blood pressure tablets. Having uncontrolled blood pressure will increase your risk of suffering a stroke, heart attack or damage to your kidneys and major blood vessels. The team of doctors involved in your care think that RDN may help lower your blood pressure.

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 United Kingdom (UK). It affects about one in 4 adults and more than half of those over 60 years old.

The cause of the majority of cases of high blood pressure is not fully understood and is generally called 'essential hypertension'.

Several different factors contribute towards essential hypertension.

These include:

- increased retention of salt and water by the kidneys
- reduced blood flow through the kidneys due to:
- nerves involved in 'stress' responses (the sympathetic nervous system)
- activity of a hormone system (the renin-angiotensin-aldosterone system).

What is the standard treatment for high blood pressure?

The standard treatment for high blood pressure in the UK is a combination of:

- blood pressure lowering medicines,
- lifestyle changes including:
 - reducing dietary salt intake;
 - keeping within recommended limits for alcohol consumption;
 - increasing exercise and losing weight where appropriate.

Despite taking medication, about half will still have uncontrolled blood pressure.

Common reasons for this include:

- Too few or insufficient doses of blood pressure medications. Sometimes people need three or more different types of medication to control blood pressure.
- Also, although some people don't tolerate higher dose of some tablets due to side effects, it is quite common for blood pressure medications to be prescribed at low doses without a good reason.

- Not taking medications regularly or in amounts suggested by your doctor. Non-adherence with medication is a common reason for uncontrolled blood pressure.
- Not making changes to lifestyle. Being overweight, not taking enough exercise and excessive salt and alcohol intake are common reasons for uncontrolled blood pressure.
- “White coat effect”. This is where blood pressure rises in response to a stressful situation, for example visiting a GP or hospital. It affects up to a third of people with apparently uncontrolled blood pressure. We identify people with white coat effect by using home or automated mobile blood pressure monitoring (also known as ambulatory blood pressure monitoring, ABPM).
- “Secondary” hypertension. Underlying causes are found in about 1 in 20 people with uncontrolled blood pressure. These are usually over-production of certain hormones or kidney artery narrowing.

Before inviting you for RDN your doctor will have ensured that you are taking an optimal combination of blood pressure lowering medication.

We will also look for and exclude:

- non-adherence to medication,
- ‘white coat effect’ and
- underlying (‘secondary’) causes.

[Will I still need to take my blood pressure medication after the denervation procedure?](#)

Although studies have demonstrated that RDN can significantly lower blood pressure, it is unlikely that RDN will enable you to stop taking your current blood pressure lowering medication altogether (if applicable). In many patients, the procedure makes the blood pressure easier to control and could also reduce the number of tablets you are taking. However, the effect is variable in patients and depends on many factors including how long you have had uncontrolled blood pressure.

Your doctor will know about the medication you are prescribed, but you know best how often you take your tablets. We may use urine samples collected in clinic to assess whether you are taking medication as recommended. If you have any problems with taking your tablets regularly please discuss these concerns with your doctor. This is important because treating blood pressure with medications has proved to be very safe and effective over the last 50 years

What does renal denervation involve?

Most people have two kidneys, each of which is supplied with blood through an artery (the kidney – or renal artery). On the outside of these arteries are small nerves (renal sympathetic nerves) which carry signals between kidneys and brain. These are the nerves we are trying to interrupt. Kidneys seem to work perfectly well doing their normal job - i.e. removing waste products and excess water from the body - without these nerves.

We have known for many years that cutting these nerves can reduce blood pressure but it has not been practical to do this until very recently. The new method of renal denervation uses a special wire fed up inside the artery from the groin. Ultrasound energy is applied to the wall of the artery from the inside and energy disrupts the nerves that run along the outside of the artery.

Is renal artery denervation safe?

Many thousands of patients have undergone RDN throughout the world and the rate of serious complications is very rare

- Bleeding and bruising in the groin area at the site of catheter insertion- around 1 in 1000, very rarely requiring blood transfusion
- Damage to the artery in the groin- 1 in 1000 requiring surgical closure
- Pain- more common, in the back and abdomen, but will settle with time
- Damage to the renal artery- very rare 2-4 per thousand would require a stent to the renal artery
- Damage to the kidneys due to the contrast material injected (dye)- very rare as the amount of dye injected is low. Usually completely recovers, very rarely will require dialysis

- Low heart rate (bradycardia), transient and often recovers
- Sudden drop in blood pressure- rare, but would require hospitalisation till it recovers.

What are the steps I have to go through for the renal denervation procedure?

- Tests and imaging that are needed

Your doctor will already have investigated you for causes of high blood pressure with a variety of scans, urine and blood tests. You will have a CT or MRI scan of your kidney arteries and an ABPM machine to make sure you are suitable for this procedure. Before your admission your doctors will have discussed your investigations and agreed that RDN is an appropriate treatment for you.

- Pre-admission visit

You will be 'seen' by one of the Consultant Interventional Cardiologists or Radiologists in a clinic. An Interventionalist is a doctor who specialises in manipulating fine guidewires and catheters within blood vessels. Usually this appointment will be at the outpatients clinic (Russells Hall hospital or Guest Outpatient clinic) You will then have a face-to-face visit with one of the team. This will happen a few days before your admission. Here we will ask you standard questions about your health as well as have pre-operative swabs. The Consultant Interventionalist will make final checks to ensure you are ready for the procedure. They will explain what the procedure involves, and ask you to sign a consent form.

Why do I need to sign a consent form?

All patients must give permission before they receive any type of medical treatment, test, or examination. Consent is usually given when you sign the consent form before your treatment, but we may ask you to give it verbally. You must give your consent voluntarily.

The hospital must give you all the information you need to make a decision about your treatment. This is so you can give us informed consent. If you have not been given this information, or you have but you still have questions, please speak to a member of staff. You must be capable of giving consent. This means that you understand the information given to you and can make an informed decision. When we

ask you to give consent, please use this time to ask any questions you may still have.

For more information, please go to the NHS Consent for Treatment web page (<https://www.nhs.uk/conditions/consent-to-treatment/>). Remember, you can withdraw your consent for treatment at any time.

Participation in a registry

Although the procedure is known to be safe, currently the NHS does not offer this procedure. The current recommendations are that it is done as part of a registry, which involves close monitoring after the procedure. You will be invited to join the registry as part of having the procedure. The registry is called the “Global Paradise System” registry. You will have frequent blood pressure monitoring and close follow up by one of the research nurses. More details regarding this will be given separately.

Preparation for the procedure

Most of this will be discussed with you during your preadmission clinic visit. However please note the following

- Fasting- We recommend that you have a light breakfast around 5AM and only sips of clear fluid after that. If your procedure is in the afternoon, you will be advised differently.
- Shaving- We recommend that you shave the top of both groins. However if you are not able to do it, we could do it for you on arrival in the ward
- Medications- We would generally recommend that you stop all blood thinning medications (Such as Warfarin, Apixaban, Rivaroxaban, Edoxaban) around 5 days prior to the procedure. You could continue to take Aspirin. This will be discussed with you during the pre-admission clinic. You will have to take all your other regular medications as usual.

Admission to hospital

You will be admitted to a bed on the Cardiology day ward on the morning of your procedure. You should bring clothes, your usual medications and other personal items for an overnight stay. You should take your usual medications on the morning of the procedure, unless advised otherwise at the pre-admission visit

Having the procedure

RDN is performed by an Interventionalist in the Cardiac Catheter lab. You will be given a painkiller and mild sedative by an anaesthetist to minimise any discomfort. However, the procedure does not need to be done under general anaesthetic.

You will lie on an x-ray table and an x-ray camera, mounted on an extendable robotic arm, is positioned over your abdomen (tummy). The Interventionalist inserts a small plastic sheath into an artery (blood vessel) at the top of your leg. This area will have first been numbed by a local anaesthetic injection, and you should feel no discomfort.

The Interventionalist uses the x-ray camera to help guide a fine catheter up into your kidney arteries. Once in position, dye is injected through the catheter to confirm the position inside the artery. A special wire is then fed through the catheter and ultrasound energy is delivered to 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 damaged.

Treating both of your arteries takes a few minutes. Rarely, we will find narrowed kidney arteries that were not seen on imaging done before the procedure. In this situation, it may not be possible to proceed to RDN.

At the end of the procedure, the catheter and sheath are removed. The puncture in the leg artery is sealed either by applying gentle pressure for a few minutes or using an arterial closure seal. An arterial closure seal, if used, will dissolve slowly over the following weeks and will not need to be removed.

Pain and pain control

During the energy bursts to the nerves many patients feel some pain or discomfort in the back or flank area. You will have been given powerful pain killers in advance and more will be given if necessary so that the discomfort is minimised.

Your team will ask you how you feel during the treatment to make sure you get enough painkiller. In a way, 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 treat. It usually passes quite quickly once the treatment has been completed.

After the procedure

Once the procedure has been complete, you will move back to the cardiology day ward. Your blood pressure and other vital signs will be

monitored for the rest of the day. You will need to remain lying flat for two hours following the procedure.

We will usually discharge you after 4 hours on the day after the procedure if you haven't had any complications and your blood pressure is stable.

After discharge from hospital

Unless we advise you otherwise, you should continue your usual blood pressure medications.

We will arrange a follow-up appointment with your blood pressure doctor. This will usually be within 2 to 6 weeks of having the procedure.

If you experience the following symptoms:

- Dizziness
- Pain in back, tummy or groin
- Excessive bleeding or bruising from the puncture site at the top of your leg

Or are otherwise concerned, you should seek advice from: Dr Nadar (via his secretary on 01384456111 Ext 4585, 8 am to 4 pm Monday to Friday; Email carolyn.whittaker1@nhs.net) Or our cardiology research nurses Alexandros Margaritis or Alexandra Florou (Tel: 01384456111 ext 3408) Dr Sherif Latif, Consultant Interventional radiologist ((via his secretary on 01384456111 ext 2541/2 or Email jayne.hyde1@nhs.net) Or Dr Shivakumar Consultant Nephrologist (Tel: 01384 244432, Email claire.miles1@nhs.net) or the cardiology day ward (Tel: 01384456111 Ext 3139) In an emergency you should seek urgent attention at your nearest emergency department, or by calling an ambulance on 999