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Study of Effects of native renal Artery denervation in Post TRANSPLANT Hypertension

Submission date
26/03/2013

Recruitment status
Stopped

Registration date
09/05/2013

Overall study status
Stopped

Last Edited
28/05/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Kidney transplantation is the best treatment for kidney failure in the majority of patients who would otherwise require dialysis. Patients who undergo kidney transplantation are still at higher risk of cardiovascular disease compared to the general population. Following transplantation, high blood pressure contributes to both cardiovascular disease and also leads to reduced kidney transplant function. Our previous work suggests that up to 80% of kidney transplant patients have high blood pressure, and in about a third of patients blood pressure is not well controlled despite medication. Renal denervation (RDN) is a new treatment for hard to treat high blood pressure. This has been shown to work in patients with normal kidney function. There is some evidence that this technique might work in kidney transplant patients as historical studies show good blood pressure control in patients who have had their original (failed or native) kidneys removed. We would like to see if using RDN as a treatment for high blood pressure in kidney transplant patients works and leads to improvements in heart structure and reduction in over activity of the sympathetic nervous system (nerves involved in fight or flight responses).

Who can participate?
Adult kidney transplant patients aged 18-85 who have had a kidney transplant for more than one year are eligible to participate. Participants should have systolic blood pressure of >140 mmHg at clinic whilst on two or more blood pressure medications.

What does the study involve?
After checking your eligibility we will arrange a baseline assessment visit. At this visit a doctor or a nurse will check your height, weight, blood pressure, current medication and medical history. Blood tests will be taken to find out about your kidney function and a variety of hormones involved in blood pressure and salt regulation. We will also request you to perform a 24-hour urine collection so we can measure salt and hormone profiles in the urine. You will undergo an ECG (heart tracing), 24-hour blood pressure monitoring, and magnetic resonance imaging (MRI), a method of looking at the structure of the heart and kidneys in detail. Measurement of muscle sympathetic nerve activity (MSNA) is an established technique used to assess the activity of the sympathetic nervous system. A small needle (much thinner than the needles used to take blood) is inserted into the peroneal nerve just below the knee. The needle is attached to a recording unit and once the nerve is located a tracing is recorded for 5 minutes.

About 1 week after the first visit you will be admitted to the renal ward. It is important to be aware that RDN is being performed on the kidneys that have already failed, and NOT your kidney transplant. RDN is performed by introducing a needle into an artery in the groin, under local anaesthetic. A small tube (catheter) is fed into the artery to perform an angiogram to take pictures of the arteries supplying the kidney. If this confirms that the arteries are suitable, the radiologist will proceed with the RDN procedure. Temporary blood thinning medication (heparin) will be infused during the procedure. Medication to relieve any anxiety and or pain will be used as required. Blood pressure and heart rate will be closely monitored throughout the procedure. The Symplicity Catheter used for the RDN procedure will be positioned in the artery to the kidney under X-ray guidance and the treatment will be performed. Upon completion, pressure will be applied to the artery in the groin to minimise any risk of bruising from the procedure. Patients will routinely stay in hospital overnight following the procedure.

1 week after the procedure you will again visit the renal transplant clinic. Medication will be adjusted to ensure your blood pressure is neither too high or too low. You will visit the clinic four more times at 1, 2, 3, 4 months after the procedure. These will also be routine visits with blood pressure, weight and blood tests performed in the usual manner with blood pressure medicine adjusted as before. At 6 months after the RDN procedure you will visit the clinic again where we will review your medication. We will also ask you to repeat the same tests as the first visit.

What are the possible benefits and risks of taking part?
RDN may improve your blood pressure and reduce your need for blood pressure medication. Taking part will help doctors understand more about high blood pressure in kidney transplant patients. Having blood taken can lead to a small bruise. With MSNA most patients experience minimal discomfort during nerve recordings. Side effects of the procedure are rare and include a tingling sensation, numbness, or pain/tenderness. Renal denervation can be painful. Every effort will be made to minimise this. Other complications may occur including bruising, pseudoaneurysm, heart rhythm disturbances, such as slow heart rate, hypotension (blood pressure too low), nausea or vomiting, atheroembolism (blockage of a blood vessel), complications associated with the dye (also known as contrast agent) used during the procedure including allergy or temporary worsening of kidney function. There is also exposure to radiation for the procedure.

Where is the study run from?
The Glasgow Renal and Transplant Unit, Western Infirmary Glasgow (UK).

When is the study starting from and how long will it run for?
From April 2013 to April 2015.

Who is funding the study?
Medtronic (UK).

Who is the main contact?
Dr Patrick Mark
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Contact information

Type(s)
Scientific

Contact name
Dr Patrick Mark

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Study of Effects of native renal Artery denervation in Post TRANSPLANT Hypertension: a non-randomised unblinded interventional study

Acronym
SERENADE-TRANSPLANT

Study objectives
We hypothesise that renal denervation (RDN), as a treatment of high blood pressure, leads to a reduction in systolic (and diastolic) blood pressure on 24-hour ambulatory blood pressure monitor in kidney transplant patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service Committee 3, 20/02/2013

Study design
Non-randomised unblinded interventional study

Primary study design
Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Renal transplantation

Interventions
Renal denervation as a treatment for hypertension, performed to the native renal arteries.

Updated 28/05/2014: this trial was stopped due to lack of funding.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary end point will be systolic blood pressure on 24-hour ambulatory blood pressure monitor

Secondary outcome measures
1. Left ventricular mass index at cardiac MRI scan at 6 months following RDN
2. Diastolic blood pressure on 24-hour ambulatory blood pressure monitor
3. Number of antihypertensive agents used
4. Renal function by estimated GFR
5. Urinary protein estimation by urinary protein: creatinine ratio

Overall study start date
01/04/2013

Completion date
01/04/2015

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria

1. Patients aged 1885 years, either sex, with a clinic systolic blood pressure of 140 mmHg or more, despite compliance with two or more antihypertensive drugs, are eligible for inclusion
2. Patients should be >12 months post renal transplantation with no evidence of rejection in past 3 months and doses of immunosuppression should be stable for >6 weeks prior to study entry

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Inability to give informed consent
2. Contraindications to MRI imaging (pacemaker, extreme claustrophobia)
3. Pregnancy and breastfeeding
4. Impaired transplant kidney function (estimated glomerular filtration rate [GFR] <30 ml/min)
5. Known secondary cause of hypertension other than renal disease (e.g. Conn's syndrome, Phaeochromocytoma etc)

Date of first enrolment
01/04/2013

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Senior Lecturer and Honorary Consultant Nephrologist
Glasgow

United Kingdom
G12 8TA

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
c/o Dr Maureen Travers
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Industry

Funder Name
Medtronic (UK)

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration