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Quality assessment of kidneys by ex-vivo warm perfusion prior to transplantation

Submission date
18/05/2016

Recruitment status
No longer recruiting

Registration date
29/06/2016

Overall study status
Completed

Last Edited
26/08/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In a healthy person, the kidneys are responsible for filtering out the waste products and excess water in the blood, and converting them into urine. If the kidneys suddenly stop working (acute kidney injury) or are suffering from severe, long-term disease of the kidneys (chronic kidney failure) then the body is unable to get rid of the waste products building up in the blood. Eventually, the kidneys are no longer able to support the body's needs (end stage renal disease) and so a treatment to replace the work of the failed kidneys is needed. Kidney transplantation is the best treatment for end-stage renal disease. Some kidneys that are donated for transplantation are deemed unsuitable for a range of reasons. The decision not to transplant a kidney relies on the judgment of an experienced surgeon but the suitability of a kidney is subject to varying opinion. Without a robust system of testing these kidneys many that may actually be suitable for transplantation are unnecessarily discarded. When kidneys are removed from an organ donor they are normally stored on ice until they are ready to be transplanted. A kidney can be preserved safely at a low temperature in these conditions. However, there is some degree of deterioration and the longer they are left in this condition the more they deteriorate (rather like food that is kept in the fridge). Furthermore, these conditions do not give us any opportunity to assess the quality of the kidney. The warm perfusion technique has been developed that offers the opportunity to test the kidney before it is transplanted. This involves placing the kidney on a machine and passing a warmed, oxygen-rich solution containing red blood cells through it for about one hour. Under these conditions the kidney can start to function again and produce urine. This allows the assessment of the quality of the kidney so it can be decided whether it can be transplanted. This testing can easily be carried out once the kidney arrives at the centre whilst the patient is being prepared for their transplant. The aim of this study is to assess the quality of kidneys that have been declined for transplantation by other transplant centres through the national allocation system and through the fast-tracking system.

Who can participate?
Adult kidney recipients and donor kidneys from deceased donors over the age of 18 which have been rejected for transplantation by several transplant centres and by all the fast-track transplant centres.

What does the study involve?
Kidneys declined for transplantation will be offered into this research study by NHSBT. If they meet the inclusion criteria they will be transplanted into a suitable recipient. Participants are prepared for surgery in the normal way. During this time the kidney is assessed using the warm perfusion technique. If the kidney is suitable for transplantation, participants are not asked to do anything or experience anything that is not standard procedure or care after receiving a transplant. There is a chance that the kidney is deemed unsuitable for transplantation and if this is the case, the transplant procedure would not go ahead. This decision may be made at the last minute after participants have been prepared for surgery. Following their transplant, participants are followed up in the usual way, which involves clinical visits at least twice a week for six weeks and then weekly for a further six weeks. Three months after the transplant a sample of the transplanted kidney is taken using a needle to look for scarring, either in Cambridge or their local centre.

What are the possible benefits and risks of participating?
Participants benefit from receiving a kidney transplant. There are no notable risks involved with participating in this study.

Where is the study run from?
1. Addenbrooke's Hospital, Cambridge (UK)
2. Guy's Hospital, London (UK)
3. Freemans Hospital, Newcastle upon Tyne (UK)

When is the study starting and how long is it expected to run for?
April 2015 to November 2020

Who is funding the study?
Kidney Research UK (UK)

Who is the main contact?
Ms Sarah Hosgood
sh744@cam.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Sarah Hosgood

Contact details
University of Cambridge
Department of Surgery
Addenbrooke's Hospital
Level 9
Hill's Road
Cambridge
United Kingdom

CB2 OQQ
+44 1223 762002
sh744@cam.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19053

Study information

Scientific Title
Quality assessment of human kidneys by ex-vivo normothermic perfusion prior to transplantation

Study objectives
The aim of this study is to assess the quality of kidneys that have been declined for transplantation by other transplant centres through the national allocation system and through the fast-tracking system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge South Research Ethics Committee, 30/06/2015, ref: 15/EE/0175

Study design
Non-randomised; Interventional; Design type: Treatment, Process of Care, Management of Care

Primary study design
Interventional

Secondary study design
Non randomised study

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
Kidney transplantation

Interventions
Kidneys declined for transplantation will be offered into this research study by NHSBT. If they meet the inclusion criteria they will be transplanted into a suitable recipient.

The patient will be prepared for surgery in the normal way. During this time the kidney will be assessed using the normothermic perfusion technology. The kidney will be perfused with a packed red blood based solution at near body temperature for 60 minutes. If suitable for transplantation, the patient will not be asked to do anything or experience anything that is not standard procedure or care after receiving a transplant. There is a chance that the kidney will be deemed unsuitable for transplantation and the transplant procedure will not go ahead.

Each patient will be followed up for 3 months post-transplant. Follow up involves normal clinical visits at least twice a week for six weeks and then weekly for a further six weeks.

At three months after the transplant we will plan to perform a routine needle biopsy of the kidney to look for scarring. This would help us with our research but it is not compulsory. Needle biopsies have a good safety record but there is a small risk (less than 1%) of significant bleeding.

Intervention Type
Other

Primary outcome measure
Graft function after transplantation is assessed by measuring serum creatinine levels over the first seven days post-transplant then one and three months after transplantation.

Secondary outcome measures
1. Rates of delayed graft function (DGF), defined as the need for dialysis within the first 7 days after transplant. Episodes of dialysis will be recorded and the need for dialysis assessed by measuring levels of creatinine in the blood. Samples will be taken daily
2. Slow graft function rate (SGF), defined as a less than 10% reduction in serum creatinine levels within for 3 consecutive days after transplantation, is measured using serum creatinine levels in the blood. Samples will be taken daily for 7 days post-transplant.
3. Rates of primary non function (PNF), defined as the graft never functioning, is measured using levels of creatinine in the blood.
4. Episodes of acute rejection within the first 3 months are diagnosed by taking a tissue sample from the kidney.
5. Adverse reactions e.g. infection, thrombosis of the graft will be recorded
6. Length of hospital stay is measured by calculating the number of days the patient remains in hospital after the transplant
7. Perfusion parameters during perfusion of the kidney (renal blood flow, urine output)
8. Histopathology, molecular markers measured in tissue samples taken from the kidney before after the transplant will be performed during the transplant procedure
9. Quality of life is measured using the Kidney disease Quality of Life – short form at baseline (before transplant) and 3 months post-transplant

Long-term secondary outcomes:
1. Graft function after transplantation is assessed by measuring serum creatinine levels at 6 and 12 months

2. Renal function is measured by determining eGFR levels at 6 and 12 months
3. Number of rejection episodes is diagnosed by taking a tissue sample from the kidney over 12 months
4. Incidences of graft loss is measured by recording the failure of the graft over 12 months

Overall study start date
01/04/2015

Completion date
04/11/2020

Eligibility

Key inclusion criteria
1. Kidneys declined for transplantation by several transplant centres and by all the fast-track transplant centres due to adverse donor characteristics, prolonged ischaemia, gross appearance, histological changes (excluding cancer), and cold perfusion parameters.
2. Donor and recipient age ≥ 18 years
3. Patient undergoing a 1st or 2nd renal transplant from a deceased donor
4. Written, signed informed consent to the procedure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Total final enrolment
21

Key exclusion criteria
1: Kidneys that are deemed unsuitable for transplantation due to contraindications defined by current NHSBT criteria .
2: Kidneys with irreparable vascular damage.
3: Recipients of a 3rd or subsequent transplant.

Date of first enrolment
21/12/2015

Date of final enrolment
01/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Hill's Road
Cambridge
United Kingdom
CB2 OQQ

Study participating centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Freemans Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust and University of Cambridge

Sponsor details
The Old Schools
Trinity Lane
Cambridge
England
United Kingdom
CB2 1TN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
Kidney Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of the study will be submitted for publication in a high-impact peer reviewed journal during the course of the study. The results will also be presented at National and International conferences.

Intention to publish date
30/11/2021

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	case report	07/06/2016	09/09/2021	Yes	No

Protocol file	version 17	16/03/2015	26/08/2022	No	No
HRA research summary			28/06/2023	No	No