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Understanding barriers and outcomes of unspecified kidney donation

Submission date
17/03/2016

Recruitment status
No longer recruiting

Registration date
03/05/2016

Overall study status
Completed

Last Edited
21/05/2020

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
The waiting list for a kidney transplant in the UK includes over 7000 people, and is increasing. The best available treatment for kidney failure is a kidney transplant from a living donor. The donor is usually a friend or relative. In 2006 donation to a stranger (referred to as unspecified altruistic donation) was introduced in the UK. Since then the number of unspecified altruistic donations has increased year on year. In 2012, 60 transplants used kidneys from unspecified altruistic donors, accounting for around 1 in 20 of all kidney transplants from living donors. These donations provide a high quality kidney to patients on the national transplant list and to someone in the paired/pooled scheme who would not otherwise obtain a transplant due to incompatibility with their donor. The number of unspecified altruistic donations varies widely across transplant centres. In 2012, three (out of a total of 23) centres accounted for 45% of all unspecified altruistic donations. There is considerable variation between centres in the proportion of people making contact in order to donate a kidney, who actually proceed to donation. Reasons for this variation are unknown but may include resource issues, concerns regarding an individual's motivations, or that the individual may develop physical or psychological issues after donation. The aim of this study is to perform a comprehensive assessment of the unspecified altruistic donor programme in the UK to explore variation between centres, and identify barriers and facilitators to donation for those that have expressed a willingness to do so.

Who can participate?
Any adult who contacts a transplant centre to enquire about donating an organ to a stranger.

What does the study involve?
Potential donors recruited into the study are asked to complete a questionnaire at four time points: one soon after they come forward as a potential donor, one before the donor operation and twice after donation (3 and 12 months after surgery). Those who do not proceed with the donation for whatever reason complete the questionnaires at the same timepoints, in order to understand more about the psychological impact of not proceeding to donation. The local living donor team is also contacted to gather further information about the donation or circumstances of the withdrawal. Three samples of 15 participants (those who donated, those who withdrew from the transplantation proceed and those who were withdrawn from the process) are also

invited to take part in an interview about their experiences that will last up to 90 minutes. The interview is with an experienced researcher and will ideally be face-to face, but may be by telephone or skype.

What are the possible benefits and risks of participating?
There are no direct benefits to participants, although participating will give them the opportunity to contribute to improved understanding of the process of unspecified donation in the UK. There is a risk that some questions that participants are asked may make them upset or distressed, however this is unlikely.

Where is the study run from?
Guys Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2015 to March 2021

Who is funding the study?
1. National Institute for Health Research (UK)
2. University of Southampton (UK)

Who is the main contact?
Anna Taylor
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20571

Study information

Scientific Title
Understanding barriers and outcomes of unspecified (altruistic) kidney donation (BOUnD)

Study objectives
The aim of this study is to perform a comprehensive assessment of the unspecified altruistic donor programme in the UK to explore variation between centres, and identify barriers and facilitators to donation for those that have expressed a willingness to do so.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Berkshire B Research Ethics Committee, 27/11/2015, ref: 15/SC/0637

Study design
Prospective mixed-methods cohort study

Primary study design
Observational

Secondary study design
Cohort 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
Focus group:
The Focus Groups represent the smallest aspect of the study and serve to help fine-tune the questionnaire design and interview topic guides. One focus group will involve those that have proceeded to donation with another of those that did not proceed. Participants will be asked about their experience of the donation process and services, barriers and enablers to donation and outcomes from either donating or withdrawing from the process.

Questionnaires:
The questionnaire part of the study will have three research populations on which questionnaire data will be collected at four intervention points (Q1-Q4): baseline, preoperatively and at 3 and 12 months post-donation or withdrawal in the form of a study questionnaire bundle. Additional data (such as gender, age or ethnic group) will be collected at the time of recruitment into the study. Follow up of these individuals will be for 12 months.

Qualitative interviews:
Qualitive interviews will be completed with a sample of 15 donors who completed their donation, 15 who withdrew and 15 who were withdrawn by the transplant team from the process. Participants will be asked about their experience of the donation process and services, barriers and enablers to donation and outcomes from either donating or withdrawing from the process. The interview questions have been informed by our previous grounded qualitative work, focus groups and current research

Intervention Type
Other

Primary outcome measure
Physical and mental health-related quality of life is measured at baseline, pre-operatively or at withrawal, 3 months post donation or withdrawal, 12 months post donation or withdrawal using:
Mental:
1. Quality of life questionnaire (SF-12)
2. General Anxiety Disorder-7 (GAD-7)
3. Patient Health Questionnaire-9 (PHQ-9)
4. Satisfaction With Life Scale
5. Rosenberg Self-Esteem Scale
6. In house questionnaire
Physical:
NHSBT pre and post donation physiological and clinical outcomes.

Secondary outcome measures
1. Barriers to donation is measured using qualitative data from interviews and focus groups at baseline, pre-operatively or at withrawal, 3 months post donation or withdrawal, 12 months post donation or withdrawal
2. Healthcare resource utilisation data is determined using the Client Service Receipt Inventory (CSRI) at baseline, pre-operatively or at withrawal, 3 months post donation or withdrawal, 12 months post donation or withdrawal

Overall study start date
16/12/2015

Completion date
31/03/2021

Eligibility

Key inclusion criteria

1. Any individual contacting a transplant centre to enquire about unspecified donation (to a stranger)
2. Those who proceeds beyond the initial phone conversation
3. Able to give informed consent, will be included as the part of the main study group

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 1085; UK Sample Size: 1085

Total final enrolment
833

Key exclusion criteria
1. Declining to participate
2. Lacking capacity to provide informated consent
3. Those not eligible to donate in the UK

Date of first enrolment
16/12/2015

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guys Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guy's and St. Thomas' NHS Foundation Trust

Sponsor details
Research & Development Dept
2nd Floor Conybeare House
Westminster Bridge Road
London
England
United Kingdom
SE1 7EH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
University of Southampton

Alternative Name(s)

University of Southampton UK

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
There will be several specific outputs in addition to published manuscripts and conference presentations:
1. A report to NHSBT and the BTS, summarising the findings of the study
2. National guidelines, produced in conjunction with NHSBT and the BTS
3. A protocol for management of those presenting for unspecified donation
4. A report to the Renal Transplant Clinical Reference Group, which reports to NHS England (which commissions transplant services in England), and to the Scottish, Welsh and Northern Irish Departments of Health

Intention to publish date
31/08/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/09/2017	23/07/2019	Yes	No
HRA research summary			28/06/2023	No	No