ISRCTN86131069 https://doi.org/10.1186/ISRCTN86131069

Assessing donor kidneys and monitoring transplant recipients

Submission date
12/12/2025

Recruitment status
Recruiting

Registration date
26/02/2026

Overall study status
Ongoing

Last Edited
21/10/2026

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Kidney transplantation is the best treatment for people with severe kidney failure, but there are not enough donor kidneys for everyone who needs one. To reduce waiting times, more kidneys from higher-risk donors (such as older donors or those who donated after circulatory death) are now being used. These kidneys are more likely to work less well after transplantation, and some recipients need to return to dialysis.
At present, doctors cannot reliably predict how well a donated kidney will work after transplantation or monitor its health without using invasive tests such as biopsies. This study aims to test whether advanced magnetic resonance imaging (MRI) scans can be used to safely and non-invasively assess donor kidneys before transplantation and monitor transplanted kidneys after surgery.
The main aim of this study is to find out whether these MRI scans are practical to perform in a real clinical setting and whether they provide useful information about kidney health that could improve transplant care in the future.

Who can participate?
Adults aged 18 years or over may be invited to take part if they are:
1. Living kidney donors donating a kidney at Oxford University Hospitals, or
2. Patients receiving a kidney transplant at Oxford University Hospitals, either from a living donor or a deceased donor.

What does the study involve?
For living kidney donors, participation involves:
1. An MRI scan of the donated kidney after it has been removed during surgery and while it is waiting to be transplanted.
2. No additional procedures or follow-up visits for the donor.
For kidney transplant recipients, participation involves:
1. One MRI scan of the transplanted kidney around 3 months after transplantation.
2. The scan lasts about one hour and does not use radiation or contrast dye.
3. Collection of routine clinical information (such as blood and urine test results) from medical

records for up to 12 months after transplantation. These tests are part of normal care and do not require extra visits.
All MRI scans are for research only and do not affect clinical decision-making.

What are the possible benefits and risks of participating?
There is no direct medical benefit to participants from taking part in this study. However, the results may help improve how donor kidneys are assessed and monitored in the future, which could benefit future transplant patients.
MRI scans are considered very safe and do not involve radiation. Some people may find the scanner noisy or uncomfortable, or feel claustrophobic. Very rarely, MRI scans may detect unexpected findings. If anything medically important is found, a doctor will review it and the participant will be informed.
There are no additional surgical procedures, injections, or changes to standard transplant care as part of this study.
The study is planned to recruit participants over approximately 12 months.
Each transplant recipient is followed for up to 12 months after transplantation, using routine clinical records and registry data. MRI scans take place before transplantation (donor kidney) and around 3 months after transplantation (recipient).

Where is the study run from?
The study is run at Oxford University Hospitals NHS Foundation Trust, in collaboration with the University of Oxford and the University of Nottingham. All participant visits and scans take place at Oxford University Hospitals.

When is the study starting and how long is it expected to run for?
December 2025 to March 2027

Who is funding the study?
Kidney Research UK

Who is the main contact?
Dr Edward Sharples, edward.sharples@ouh.nhs.uk

Contact information

Type(s)
Scientific, Public

Contact name
Prof Maria Kaisar

Contact details
Nuffield Department of Surgical Sciences, John Radcliffe Hospital, Headington
Oxford
United Kingdom
OX3 9DU
+44 1865223872
maria.kaisar@nds.ox.ac.uk

Type(s)
Principal investigator, Public

Contact name
Dr Edward Sharples

Contact details
Oxford transplant centre, Churchill Hospital, Old Road, Headington
Oxford
United Kingdom
OX3 7LE
+44 1865 223872
edward.sharples@ouh.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
344942

Central Portfolio Management System (CPMS)
69266

Study information

Scientific Title
Assessing donor kidneys and monitoring transplant recipients

Acronym
ADMIRE

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/07/2025, South Central - Oxford A Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 1048241; oxforda.rec@hra.nhs.uk), ref: 25/SC/0216

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Basic science, Device feasibility, Diagnostic

Study type(s)

Health condition(s) or problem(s) studied
Adult kidney transplant recipients, living kidney donors and deceased donor organ offers.

Interventions
Donor organ ex-vivo MRI scans in a 3 Tesla MRI scanner:
MRI measures will comprise high spatial resolution relaxometry maps (T1: ultrafast-gradient-echo; T2: GRASE; T2*: multi-shot-FFE), DWI and DTI images, and MTR data. We will perform quantitative susceptibility mapping (QSM; sensitive to cellular arrangement and tissue microstructure and collect ultra-high resolution T2*-weighted and T1-weighted images.

Post-transplant MRI scans:
A 3 Tesla MRI scanner at the radiology department in OUH will be used to perform multiparametric renal MRI of the participants. The protocol includes:
Localizer and structural scans.
Longitudinal (T1) relaxation time mapping: A respiratory-triggered inversion recovery (IR) SE-EPI scheme or shortened MOdified Look-Locker Inversion recovery (ShMOLLI) scheme will be used.
Diffusion weighted imaging (DWI) to determine apparent diffusion coefficient (ADC), as well as fitting an IVIM model.
Phase Contrast MRI (PC-MRI): Renal artery blood flow in the right and left renal arteries will be measured in a breath hold using a single slice perpendicular to the renal artery. A non-contrast enhanced MR angiogram will determine renal artery bifurcations and aid PC- MRI slice placement.
Arterial spin labelling (ASL): There are a number of approaches to renal ASL to assess renal perfusion, comprising different labelling schemes (FAIR or pCASL labelling scheme) and readout protocols (for example, EPI versus balanced fast field echo (bFFE) schemes).
Blood Oxygen Level Dependent (BOLD) mapping: This provides a measure of changes in renal oxygenation (9): BOLD R2* data will be acquired using a multi-echo fast field echo (mFFE) scheme.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
ex-vivo multi-parametric MRI and post-transplant multiparametric renal MRI

Primary outcome(s)
1. Approach-for-consent to consent ratio measured using screening log records at day 0 during cold storage of donor organ after arrival to Oxford, prior to transplantation

2. Enrolment to actual ex-vivo MRI scanning ratio measured using screening log records at day 0 during cold storage of donor organ after arrival to Oxford, prior to transplantation

3. Kidney cold ischaemia time (time from cold perfusion in the donor to reperfusion with recipient's blood) measured using time recording in organ log at day 0 during cold storage of donor organ after arrival to Oxford, prior to transplantation

4. MRI Scan performed as per designed protocol measured using recording confirmation by MR radiographer at day 0 during cold storage of donor organ after arrival to Oxford, prior to transplantation

5. Median time in Oxford (Time kidney arrives in Oxford, Time kidney taken to theatre, Time kidney reperfused with recipient's blood) measured using time recording in organ log at day 0 during cold storage of donor organ after arrival to Oxford, prior to transplantation

6. Median time from sign-out for scanning to scan completion measured using time recording in organ log at day 0 during cold storage of donor organ after arrival to Oxford, prior to transplantation

Key secondary outcome(s)

Completion date
31/03/2027

Eligibility

Key inclusion criteria
Organ-offer criteria:
1. Kidney-only offer from living or deceased donors, including both Donation after Circulatory Death (DCD) or Donation after Brain Death (DBD) donors.
2. Accepted for transplantation according to standard clinical selection criteria.
3. Donor/family/next of kin consent for research.

Recipient criteria:
1. Male or Female aged 18 years or above.
2. Recipient participant who is admitted as a recipient of a kidney transplant.
3. Recipient participant is willing and able to give informed consent for participation in the study.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex

All

Total final enrolment
0

Key exclusion criteria
Organ-offer criteria:
1. Donor organs accepted Kidney transplants which are part of any other simultaneous transplant, such as simultaneous pancreas kidney or modified multi-visceral transplants.

Recipient criteria:
1. Unwilling or unable to comply with the requirements of this protocol including the presence of any condition (physical, mental, or social) that, in the opinion of the PI, is likely to affect the recipient participants ability to comply with the study protocol.
2. Recipient participant has any contraindication to MRI (including pregnancy).

Date of first enrolment
12/12/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford Transplant Centre, Oxford University Hospitals
Churchill Hospital, Old Road, Headington
Oxford
England
OX3 7LE

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type

Funder Name
Kidney Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All trial data will be entered on an electronic CRF. This will be hosted on RedCap.
The participants will be identified by a unique trial specific number and/or code in any database. The name and any other identifying detail will NOT be included in any trial data electronic file.
No identifiable, personal data will be retained centrally (i.e. by the sponsoring organisation), but rather this will be held separately from the research data at individual sites only.
The data management will follow the University of Oxford's Information Security Handling Rules @ https://www.infosec.ox.ac.uk/asset-management
The Data Protection Checklist https://researchsupport.admin.ox.ac.uk/policy/data/checklist has been followed while developing the protocol and PIS, the data sharing with the University of Nottingham is necessary as they developed a unique MRI protocol and the co-investigators there are necessary to the analysis and as such the output of our study.

Personal Data will be retained by the site (Oxford University Hospitals) for no more than 12 months, after which Personal Data will be destroyed. Research data (including the consent forms) will be retained for a period of 7 years following the end of the study.

We plan to send all the MRI scans to University of Nottingham as they are the MR physicists in the investigator team who will perform the primary analysis of the MRI data. The MRI data will be pseudonymised with the study ID (e.g. ADMIRE001 and only year of birth) before upload of the DICOM data.

The MRI data will be shared with University of Nottingham using XNAT which is hosted in Nottingham. The server itself is a physical machine securely hosted within the University of Nottingham Data Centre. Data transfer will use secure encrypted protocols (HTTPS), The system

is designed to store data securely and provides functionality for fine grained individual access control, data updating and/or removal that are required for compliance with GDPR principles. No data will be shared outside of the universities of Oxford and Nottingham.

Practical Considerations consulted can be accessed on
https://researchsupport.admin.ox.ac.uk/policy/data/practical

The datasets generated during and/or analysed during the current study will be stored in secure, access-controlled institutional repositories at the University of Oxford and collaborating institutions (including the University of Nottingham).

The data include pseudonymised multiparametric MRI imaging data of donor kidneys and transplant recipients, together with linked clinical outcome data (e.g. serum creatinine, estimated glomerular filtration rate, urine albumin-to-creatinine ratio, and transplant outcomes). MRI imaging data are potentially identifiable by nature, even after removal of direct identifiers.

Data will be available after completion of the study and publication of the primary results and will be retained in accordance with institutional and funder data-retention policies (minimum 7 years, with imaging data archived for quality control and approved future research use).

Access will be limited to qualified researchers and granted only for ethically approved research purposes via a formal data-sharing agreement, following review by the study investigators. Participant consent for controlled research use and data sharing was obtained. Public deposition is not appropriate due to data protection, confidentiality, and re-identification risks, particularly for MRI data.

The datasets generated during and/or analysed during the current study will be available upon reasonable request from:
Associate Professor Maria Kaisar
University of Oxford
Email: maria.kaisar@nds.ox.ac.uk

Available data include pseudonymised MRI imaging data and associated clinical outcome data. Data will be available after publication of the primary study results and for the duration of the institutional data-retention period.

Requests will be considered from academic or clinical researchers proposing scientifically valid, non-commercial analyses consistent with the original ethical approvals and participant consent. Access will require appropriate ethical approval (where applicable) and a data-sharing agreement. Data will not be shared in a form that permits participant identification, and legal and ethical restrictions under UK GDPR and NHS research governance apply.

IPD sharing plan summary

Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Consent form version 1.0	13/06/2025	15/12/2025	No	No
Participant information sheet	version 1.0	13/06/2025	15/12/2025	No	Yes