ISRCTN21516608 https://doi.org/10.1186/ISRCTN21516608

A trial examining if less fluid administration is better than standard fluid administration in children undergoing kidney transplant

Submission date
09/07/2025

Recruitment status
Recruiting

Registration date
21/07/2025

Overall study status
Ongoing

Last Edited
11/08/2025

Condition category
Surgery

[ ] 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 treatment of choice for children with established kidney failure. Children having a kidney transplant receive fluid by a drip, both during and after the operation. The best amount of fluid for children with a new transplant is not known. Too little fluid can cause delays in the kidney transplant working, or blood clots in the transplant. Too much fluid can cause breathing difficulties, swelling, high blood pressure, headaches or fits. These problems are important to patients and take up valuable specialist NHS resources. There is a pressing need to work out the best amount of fluid for children having a kidney transplant. We are a group of kidney doctors, surgeons, a psychologist, parents, young people and trial experts working together on the LIMITS research study to answer this question. Our aim is to find out whether children having kidney transplants should have a limited amount of fluid given according to their body size, or the larger volumes of fluid that are usually given. Following input from parents and young people a key aim of this research is helping children spend more time at home after transplant.

This study will help to work out the best amount of fluid for children after kidney transplant. This could speed up children's recovery, improve their experience of transplant and free up specialist NHS resources. It therefore has the potential to change clinical practice and importantly improve the treatment and outcomes of children receiving kidney transplants in the UK. We will publish the results in a widely read medical journal and present them at conferences and on the study website.

Who can participate?
Any child or young person who is receiving a kidney-only transplant from either a living or deceased donor in a participating UK centre may participate. The child or young person must be under the age of 18 years at the time of kidney transplantation.

What does the study involve?
The study will compare recovery in children having different amounts of fluid after kidney transplant. Some children will receive the large amounts that doctors usually give. For others,

we will limit the amount of fluid given according to their body size. An independent process called randomisation will decide which fluid amount each child receives. The fluid will be given through a vein (intravenously), by mouth (enterally) or by the child's usual route. All transplant recipients are given intravenous fluids or enteral fluids during their admission, so this is not an additional burden for trial participants. There will be no study specific blood samples and no extra study visits beyond routine clinical follow up. Blood tests will be done as per standard care with options for mild topical anaesthetics and use of distraction techniques. We will assess children's recovery by the number of days spent at home (rather than in hospital) after transplant. We will work out the impact on health and health service costs from limiting fluid compared to usual practice.

We hope that 140 children from the 10 UK children's kidney transplant hospitals will take part over 2 years. This number is calculated to ensure that the study is large enough to reach a firm conclusion. Children who agree to join the study will be split into 2 equal groups. Depending on what group the child is in, they will receive either usual amounts of fluid, or a limited amount of fluid tailored to their body size. We will ask children and parents to report their symptoms and experience of their transplant hospital stay.

What are the possible benefits and risks of participating?
Possible benefits:
Research participants may experience less unpleasant symptoms from fluid overload (i.e. less swelling, shortness of breath, headache and fits) and subsequently avoid further intervention to investigate and treat these symptoms which could be uncomfortable or cause psychological distress (i.e. additional medications, blood transfusion, oxygen, additional investigations such as chest x-ray). They may potentially go home earlier after kidney transplant so spend less time in hospital.

Possible Risks:
There are few risks to taking part in this trial, above the risk of kidney transplantation itself. The key risks of liberal fluid administration (current majority practice) are related to fluid overload and are:
• high blood pressure which can lead to headaches and seizures
• fluid on the lungs (pulmonary oedema) which can lead to difficulty breathing
• electrolyte disturbance which can lead to fits (seizures)
• increased blood transfusions
• unexpected intensive care or high dependency unit admission

Some clinicians expressed concern about delayed transplant function and/or thrombosis with a capped fluid approach but this risk is not evidenced-based. Observational data in paediatric kidney transplant recipients <20kg have shown favourable outcomes with less liberal intra-operative fluid volume administration. There is no evidence base for the current liberal use of fluid.

These risks will be mitigated by frequent monitoring of clinical observations. If identified, prompt investigation and treatment will be commenced. This practice will be followed in both arms of the clinical trial. In summary, the risks of participating in the study are not felt to be greater than those of standard clinical care.

Where is the study run from?
Great Ormond Street Hospital for Children NHS Foundation Trust (UK)

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

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
Dr Wesley Hayes, chief investigator, Wesley.Hayes@kispi.uzh.ch
Dr Nuala Calder, clinical research fellow, n.calder@ucl.ac.uk
Dr Fotini Kaloyirou, trial manager, fotini.kaloyirou@nhsbt.nhs.uk

Study website
https://www.nhsbt.nhs.uk/clinical-trials-unit/trials-and-studies/organ-donation-and-transplantation/limits/

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Dr Wesley Hayes

Contact details
Great Ormond Street Hospital
London
United Kingdom
WC1N 1EH
+41 78 326 1236
Wesley.Hayes@kispi.uzh.ch

Type(s)
Public

Contact name
Dr Fotini Kaloyirou

Contact details
NHSBT CTU
Long Road
Cambridge
United Kingdom
CB2 0PT
+44 7385388072
fotini.kaloyirou@nhsbt.nhs.uk

Type(s)
Scientific

Contact name

Dr Nuala Calder

Contact details
Bristol Royal Hospital for Children, Paediatric Nephrology Department, Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ
+44 7385388072
n.calder@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
354370

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR206591, CPMS 69346

Study information

Scientific Title
A randomised multiple centre trial of conservative versus liberal fluid administration for children receiving a kidney transplant

Acronym
LIMITS

Study objectives
A relative limitation of fluid volume administered to children receiving kidney transplant is superior to usual liberal fluid volume administration in terms of days at home to 30 days after transplant.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 19/06/2025, Cambridge South REC (The Old Chapel Royal Standard Place , Nottingham , NG1 6FS, United Kingdom; +44 207 104 8084; cambridgesouth.rec@hra.nhs.uk), ref: 25/EE/0161

Study design
Apragmatic multicentre open label randomized controlled trialwith internal pilot phase and integrated economic evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Efficacy

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

Health condition(s) or problem(s) studied
Fluid management in paediatric kidney transplantation

Interventions
Summary of treatment in each group:
- Intervention: Fluid volume administration capped at maximum 150ml/m²/hour for no longer than 18 hours following transplant, reduced to a fixed daily target of maximum 1.5 litres/m²/day thereafter. No specific urine output will be targeted. No diuretics to be administered throughout.
- Comparator: Target urine output >2ml/kg/hour. Fluid administered to replace urine output + insensible losses for at least 48 hours. Diuretics per the clinical team's usual practice.

Follow up period:
Follow up data up will be collected up to 3 months post-transplant.

Randomisation:
Eligible patients who have consented to participate in LIMITS will be randomised via an interactive web response system, provided by Sealed Envelope. Participants will be randomised in a 1:1 ratio, to the intervention and comparator groups. The randomisation will be stratified by transplant centre and donor type (deceased vs. living donation). Randomisation will further be balanced within blocks of varying, undisclosed sizes.

Intervention Type
Other

Primary outcome measure
Mean days at home in the first 30 days after kidney transplant measured using patient records

Secondary outcome measures
1. Patient-reported experience of transplant hospital stay (from admission to discharge)
2. Proportion of participants with systemic hypertension (systolic blood pressure above the 95th centile for age and height on 2 consecutive days) within 7 days after transplant
3. Proportion of participants with pulmonary oedema on chest x-ray within 7 days after transplant
4. Proportion of participants with severe acute hyponatraemia (plasma sodium concentration

<130mmol/l) within 7 days after transplant
5. Proportion of participants receiving a red blood cells within 7 days after transplant
6. Proportion of participants with transplant thrombosis in the post-operative period leading to graft failure within the first 30 days
7. Proportion of participants with delayed transplant function (dialysis within the first 7 days after transplant)
8. Mean transplant function measured by estimated glomerular filtration rate at 3 months post-transplant
9. Cost-effectiveness analysis: kidney-related costs within the study period (all costs incurred and implications for patient health within the study.)

Overall study start date
01/01/2025

Completion date
30/12/2027

Eligibility

Key inclusion criteria
1. Children under 18 years of age at the time of transplantation with valid informed consent
2. Children receiving a kidney only transplant from either a living or deceased donor, in a participating UK centre

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Months

Upper age limit
18 Years

Sex
Both

Target number of participants
140

Key exclusion criteria
Multi-organ transplant recipients

Date of first enrolment
01/06/2025

Date of final enrolment
31/05/2027

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Study participating centre
Great Ormond Street Hospital for Children
Great Ormond Street
London
United Kingdom
WC1N 3JH

Study participating centre
Evelina London Children's Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Bristol Royal Hospital for Children
Paul O'Gorman Building
Upper Maudlin Street
St Michael's Hill
Bristol
United Kingdom
BS2 8BJ

Study participating centre
Birmingham Childrens Hospital
Steelhouse Lane
St. Chads Tunnel
Birmingham
United Kingdom
B4 6NH

Study participating centre
Royal Manchester Childrens Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Leeds Children's Hopsital
Clarendon Wing
Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Study participating centre
Royal Hospital for Sick Children (Glasgow)
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Great North Children's Hopsital
Victoria Wing
Royal Victoria Infirmary
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Nottingham Children's Hospital
Queen's Medical Centre,
Derby Road
Lenton
Nottingham
United Kingdom
NG7 2UH

Study participating centre

The Royal Belfast Hospital for Sick Children
274 Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

Sponsor details
Great Ormond Street
London
England
United Kingdom
WC1N 3JH

+44 (0)207 905 2271
vanshree.patel@gosh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.gosh.nhs.uk/

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Results and Publications

Publication and dissemination plan
All research teams and PPI members involved in the study will be invited to a close out meeting to discuss the findings of the study. Study findings will be presented to academic and non-academic groups. The PPI group will play an important part in disseminating the study findings into the public domain. Dissemination to non-academic audiences including service users, commissioners, clinicians and service providers will be facilitated through the use of existing networks e.g. email lists, social media.

Open access, peer reviewed academic outputs and research reports together with associated summaries and key findings will be produced for funders, policy makers and NHS audiences and held on the study website.

Intention to publish date

30/12/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from NHSBT Clinical Trials Unit (ctu@nhsbt.nhs.uk).
The type of data: fully anonymised analysis dataset.
When the data will become available and for how long: 9 months after publication and ending 5 years following article publication.
By what access criteria data will be shared including with whom: Data will be shared with investigators whose use of the data has been assessed and approved by an NHSBT review committee and the Sponsor as a methodologically sound proposal. A full Data Sharing Request form will be required.
For what types of analyses, and by what mechanism: to be agreed before data is shared
Whether consent from participants was obtained: Data of participants who have not agreed to the use of their data for future research, will be removed from the dataset.
Comments on data anonymisation: data will be anonymised prior to sharing.
Any ethical or legal restrictions: none.
Any other comments: a contract is mandatory before any data is shared with a third party.

IPD sharing plan summary

Available on request