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Infant kidney dialysis and filtration: the I-KID study

Submission date
27/11/2017

Recruitment status
No longer recruiting

Registration date
28/06/2018

Overall study status
Completed

Last Edited
19/01/2024

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Babies in Paediatric Intensive Care Units (PICUs) may be so unwell, such as after having surgery, or with sepsis, that their kidneys are temporarily not working well. When this happens, some babies may need help with their kidney function by using a type of dialysis. There are a few different methods of dialysis used in hospitals as part of standard care: peritoneal dialysis (PD) where fluid is cycled in and out of the abdomen, and haemodialysis /filtration where blood is removed by a machine and cleaned as it passes through a dialysis circuit. Using the existing dialysis methods in PICU, there are problems treating the smallest babies (under 8 kg), of which there are about 300 each year in the UK. PD has a limited ability to clean blood and remove fluid and is prone to complications like leaking, blockage, and infection. Haemodialysis machines used as standard at the moment have been adapted from systems for adults and larger babies. They have been given a CE mark (approval to be sold and used in any country in Europe) to treat children who weigh 8 kg or more. They are not really suited for smaller babies, but clinicians do have a lot of experience in using them for babies and have adapted them. The NIDUS machine is the newest method and was developed in Newcastle upon Tyne. It has been designed and made especially for small babies who weigh less than 8 kg who are having dialysis in a PICU. Having seen the results so far, some doctors across the UK have asked to use the NIDUS for small babies in their own hospital. As it is new, the aim of this study is to compare the NIDUS machine with the other existing dialysis methods in order to say which method is better and should be used in the future.

Who can participate?
Babies in PICU with a body weight of 0.8 – 7.99 kg who require continuous dialysis as part of their standard clinical care

What does the study involve?
Participating hospitals are randomly allocated to a treatment sequence. Each sequence starts with a control period (conventional dialysis), followed by training, then by the intervention period (NIDUS). During the control period, the clinical team determines which conventional method of dialysis is most appropriate for the baby in line with local practice. During the intervention period, the NIDUS machine is used instead of conventional therapy before the patient starts dialysis. During both periods data is collected including weighing of dialysate fluid

and testing of waste dialysate fluid. Data collection stops either when the patient stops dialysis, or 28 days after dialysis is started if this is sooner. Some data is also collected at discharge from the PICU. There is a 1-month follow-up after dialysis is started in line with the local practice hospital visit (but no longer than 3 months after).

What are the possible benefits and risks of participating?
Each baby will still receive dialysis whether they are in the study are not. At the moment there are no fully approved machines for use in very small babies as they have been adapted using adult methods. The babies taking part may be able to receive dialysis using the NIDUS machine if it is being used in the PICU at that time and if consent is received from the parent/legal guardian. Whatever form of dialysis each baby receives they will be even more carefully looked after whilst they are in the study.

Where is the study run from?
1. The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)
2. University Hospital Southampton NHS Foundation Trust (UK)
3. University Hospitals Bristol NHS Foundation Trust (UK)
4. Birmingham Women's and Children's NHS Foundation Trust (UK)
5. Great Ormond Street Hospital for Children NHS Foundation Trust (UK)
6. Guy's and St Thomas' NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2015 to February 2022

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
36558, CIV-GB-18-02-023105

Study information

Scientific Title
I-KID: Infant KIdney Dialysis and filtration: evaluation of efficacy, outcomes and safety of a new infant haemodialysis and ultrafiltration machine in clinical use

Acronym
I-KID

Study objectives
Fluid balance control will be improved using NIDUS with good clearances and fewer adverse effects than conventional renal replacement therapy (RRT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East – Tyne & Wear South Research Ethics Committee, REC Approval with Conditions 08/02/2016, REC Acknowledgment of Conditions Met 17/04/2018

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment, Device

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute renal insufficiency or fluid overload

Interventions
I-KID is looking to find out which method of dialysis gives the best support to very small babies. 6 NHS Trusts in England have agreed to take part and collect information on babies treated with both existing dialysis methods and with the new NIDUS machine. The NIDUS has been developed in Newcastle upon Tyne and designed especially to provide kidney support for babies who weigh less than 8 kg.

Each participating site will be randomised to a treatment sequence in the stepped wedge design. Each sequence starts with a control period (conventional dialysis), followed by training, then by the intervention period (NIDUS).

The initial decision to commence dialysis will be clinical. During the control period, the clinical team will determine which conventional method of dialysis is most appropriate for the baby in line with local practice. During the intervention period, consent will be taken to use the NIDUS machine instead of conventional therapy before the patient starts dialysis. For both periods, consent will be taken for the collection and recording of data (routine and additional), weighing of dialysate fluid and clinical biochemistry testing of waste dialysate fluid.

Data collection for the primary outcome measure is during the first 48 hours after RRT starts. Data collection for secondary outcome measures will stop either when the patient stops dialysis, or 28 days after dialysis was started if this is sooner. Some data will also be collected at discharge from PICU. There will be an approximately 1-month follow-up after dialysis was started in line with the local practice hospital visit (but no longer than 3 months after).

Phase 1 (0 hours to +6 hours): between dialysis day 1 time 0 and as close to +6 hours as is practically possible.
Phase 2 (+6 hours to 48 hours): after the first 6 hours of dialysis at fixed 12 hourly intervals e.g. 08:00 and 20:00 until 48 hours has lapsed from the start of dialysis.
Phase 3 (0 hours until RRT stops, or 28 days after RRT): between dialysis day 1 time 0 until the patient stops dialysis, or 28 days after dialysis was started if this is sooner.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The accuracy of dialysate fluid removal compared with prescription as measured by the following:
For CVVH/D or NIDUS: weighing the dialysis bags at the beginning and end of a study period lasting as close to +6 h as is practically possible (tolerance 5 to 7 h) during phase 1 to identify the quantity of fluid removed, compared to the quantity that the clinicians prescribed to be removed
For PD: volumetric measuring by the nursing staff of the volumes of dialysis fluid run into, and subsequently drained, from the babies' abdomens during a complete number of dialysis cycles over a study period lasting as close to +6 h as is practically possible (tolerance 5 to 7 h) during phase 1 to identify the quantity of fluid removed, compared to the quantity that the clinicians prescribed to be removed

Key secondary outcome(s)
1. Haemodynamic status (drop in blood pressure after connection requiring intervention), measured by the PICANet daily and enhanced data
2. Biochemical clearances, measured by clinical biochemistry testing (enzymatic creatinine, urea, phosphate) on the sample of waste dialysate fluid collected) at the same time the routine bloods are sent to the local laboratory for analysis during phase 1 and 2
3. Number of ventilator free days, measured/recorded in the PICAnet (daily and enhanced data) collected during phase 1, 2 and 3
4. Survival, measured at 1 month follow up (no longer than 3 months)
5. Completion of intended renal replacement therapy course, measured/recorded in the PICAnet (daily and enhanced data) collected during phase 3
6. Need for additional vascular or dialysis access, measured/recorded in the PICAnet (daily and enhanced data) collected during phase 1, 2 and 3
7. Unplanned change in circuits, measured in the PICAnet (daily and enhanced data) collected during phases 1, 2 and 3
8. Exposure to blood transfusion: extra clinical data, in addition to PICAnet, recorded during

phase 1, 2 and 3
9. Bleeding events, measured/recorded in the PICAnet (daily and enhanced data) collected during phase 1, 2 and 3
10. Anticoagulant use, measured/recorded in the PICAnet (daily and enhanced data) collected during phase 1, 2 and 3
11. Parent/guardian experience, measured using questionnaires at an appropriate time before the patient is discharged from the PICU (any time up to the day of discharge)
12. Staff acceptability and usability of device, measured by questionnaire completion by staff who are using the NIDUS machine during the first 48 hours of dialysis

Completion date
28/02/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 25/09/2019:
1. Patients in PICU with a body weight of 0.8-7.99 kg who require continuous RRT for acute renal insufficiency or fluid overload as part of their standard clinical care
2. Person with legal parental responsibility (PR) for the patient has provides written informed consent for the patient to take part in the study. This may be after the patient has started dialysis in an emergency situation to not delay any treatment.

Previous inclusion criteria:
1. Patients in PICU with a body weight of 0.8 kg – 7.99 kg who require continuous RRT for acute renal insufficiency or fluid overload as part of their standard clinical care
2. Person with legal parental responsibility (PR) for the patient has provided written informed consent for the patient to take part in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
97

Key exclusion criteria
1. Patient with known chronic renal failure already on adequate RRT
2. Patient already established on adequate RRT for whom entry into the study would require additi

3. Patient has an underlying metabolic diagnosis, including hyper ammonaemia

4. Clinician makes a clinical decision that the patient should not receive RRT using NIDUS
5. Unable to receive written informed consent for data collection from a person with legal PR for tl

Date of first enrolment
01/10/2018

Date of final enrolment
31/07/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Royal Victoria Infirmary
Queen Victoria Road
New Victoria Wing
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Study participating centre
University Hospital Southampton NHS Foundation Trust
Mail Point 27
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
University Hospitals Bristol NHS Foundation Trust
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Study participating centre

Birmingham Women's and Children's NHS Foundation Trust
Birmingham Children's Hospital
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

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

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Evelina London Children’s Hospital
Westminster Bridge Rd
St Thomas’ Hospital
London
United Kingdom
SE1 7EH

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Rd
High Heaton
Newcastle upon Tyne
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NE7 7DN

Sponsor information

Organisation
The Newcastle Upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Efficacy and Mechanism Evaluation Programme

Alternative Name(s)
NIHR Efficacy and Mechanism Evaluation Programme, Efficacy and Mechanism Evaluation (EME), EME

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/03/2023	13/03/2023	Yes	No
Results article		01/01/2024	19/01/2024	Yes	No
Protocol article		18/10/2021	19/01/2024	Yes	No
HRA research summary			13/03/2023	No	Yes
Participant information sheet	version 4.0	07/10/2019	13/03/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (preprint)		16/07/2021	13/03/2023	No	No
Protocol file	version 7.0	08/04/2021	13/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes