Infant kidney dialysis and filtration: the I-KID study

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
27/11/2017		[X] Protocol		
Registration date	Overall study status	[] Statistical analysis plan		
28/06/2018	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant dat		
19/01/2024	Urological and Genital Diseases			

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? Shriya Sharma Shriya.Sharma@newcastle.ac.uk

Study website

https://research.ncl.ac.uk/i-kid/i-kidinformation/whatisi-kidabout/

Contact information

Type(s) Scientific

Contact name Ms Shriya Sharma

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

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

Primary study design Interventional

Secondary study design Cluster randomised trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

https://fundingawards.nihr.ac.uk/award/14/23/26

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2015

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

Age group

Neonate

Sex Both

Target number of participants Planned Sample Size: 95; UK Sample Size: 95

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 th

Date of first enrolment 01/10/2018

Date of final enrolment 31/07/2021

Locations

Countries of recruitment England

United Kingdom

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 United Kingdom NE7 7DN

Sponsor information

Organisation The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Sponsor details c/o Sean Scott, Regulatory Compliance Manager Freeman Hospital Freeman Road High Heaton Newcastle-Upon-Tyne England United Kingdom NE7 7DN +44 (0)191 2824461 sean.scott@nhs.net

Sponsor type Hospital/treatment centre

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, EME

Funding Body Type Government organisation

Funding Body Subtype National government

Results and Publications

Publication and dissemination plan

The protocol will be available asap on the funder website (https://www.journalslibrary.nihr.ac.uk /programmes/eme/142326/#/). It has not yet been published.

The results of this study will be published in a number of reports (publications) in medical journals to inform other doctors, nurses, parents and the public to learn more about dialysis in small babies. Data from the study may also be presented at meetings and shared with other researchers.

Intention to publish date

31/12/2022

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