ISRCTN55761337 https://doi.org/10.1186/ISRCTN55761337

Comparison of haemodialysis and peritoneal dialysis in babies

Submission date
17/08/2011

Recruitment status
No longer recruiting

Registration date
07/11/2011

Overall study status
Completed

Last Edited
03/03/2016

Condition category
Urological and Genital Diseases

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
The control systems of conventional haemodialysis (HD) machines are not sufficiently refined for them to be recommended for use in babies weighing less than 8 kg. Therefore, most small babies who develop acute kidney failure are treated with peritoneal dialysis (PD), which produces lower clearances and unpredictable fluid removal compared to the HD method. We have developed the Newcastle infant HD machine especially for small babies. It has a different circuit and gives high clearances and precisely controlled fluid removal. We want to find out first whether the Newcastle HD machine will provide better clearance of the kidney marker creatinine than PD does in small babies. This is an important question because it may be more reliable to use the Newcastle HD machine than PD in the future. We also want to find out whether PD or the HD machine will provide greater clearances of the chemicals urea and phosphate from the babies, whether it will provide greater and more precise control of fluid removal than PD, and whether it will be more convenient to manage and as safe.

Who can participate
Babies weighing less than 8 kg treated in the Freeman Hospital Paediatric Intensive Care Unit

What does the study involve?
Most babies are likely to have developed their acute kidney failure after recent open-heart surgery. Each baby will be treated on alternate days for 4 days with either PD or HD, and we will measure how well these treatments clear chemicals and fluids, and assess the medical and nursing views of their convenience to use, as well as monitoring for safety. There will be 2 possible treatment sequences: sequence 1 will start with PD, then HD,PD,HD,PD, and sequence 2 will start with HD, then PD,HD,PD, HD.

What are the possible benefits and risks of participating?
The babies will not need any extra dialysis access surgery, nor extra anti-coagulation medicines, as eligible babies will already have these routinely. They will not need any extra blood sampling episodes (which are in any case through a central line), though some extra blood will be taken during the existing sampling times, totalling 4 ml from each baby. The infant HD machine has

been totally stable and reliable during extensive in-vitro testing, and has not produced any adverse events whilst being used to study 7 piglets, nor while being used for a total of 6 months on 2 babies who had no therapeutic alternatives available.

Where is the study run from?
The Freeman Hospital Paediatric Intensive Care Unit (UK)

When is the study starting and how long is it expected to run for?
January 2012 to December 2013

Who is funding the study?
The HD machines have already been designed, developed, built and used in clinically urgent cases on humanitarian grounds; there are no funding issues for these. Other costs are being met from a charitable research grant. The study is sponsored by the Newcastle upon Tyne Hospitals NHS Foundation Trust

Who is the main contact
Dr Malcolm Coulthard
malcolm.coulthard@nuth.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Malcolm Coulthard

Contact details
Department of Paediatric Nephrology
Royal Victoria Infirmary
Queen Victoria Road
Newcastle
United Kingdom
NE1 4LP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A crossover trial of dialysis efficiency in babies weighing up to 8kg, comparing peritoneal dialysis with haemodialysis using the Newcastle infant haemodialysis machine

Study objectives
We will treat babies weighing up to 8kg with both haemodialysis (HD) using the new Newcastle infant haemodialysis machine, and with conventional peritoneal dialysis (PD), to compare their efficiency, safety, and convenience of use in the same infants.

The null hypothesis for the primary outcome measure will be that the HD machine will be no better than PD, and the alternative hypothesis is that it will be provide greater clearances of the waste chemical creatinine.

The null hypothesis for the secondary outcome measures will be that the HD machine will be no better than PD, and the alternative hypothesis is that it will be provide greater clearances of the waste chemicals urea and phosphate, and that it will provide more precise control of fluid removal, that it will be equally safe, and that it will be less time consuming and more convenient for the nursing staff to operate than PD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Crossover group-sequential trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

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
Acute kidney failure in babies weighing <8 kg

Interventions
Babies weighing up to 8 kg that need dialysis for acute renal failure and who would normally be treated with peritoneal dialysis (PD), will be studied for 4 days. During that time they will have 2

days of PD, and 2 days of haemodialysis (HD) with a new infant haemodialysis machine. The different treatments will be given on alternate days, and the starting modality will be randomised. Comparisons will be made within patients a crossover design.

The only extra interventions they will undergo will be a total of 4ml blood being drawn at times that blood was being sampled for clinical reasons (to test for plasma haemoglobin concentrations), and chemical analysis of waste dialysis fluid to allow clearances to be measured.

Intervention Type
Procedure/Surgery

Primary outcome measure
Our primary question is whether the Newcastle HD machine will provide better clearance of the kidney marker creatinine than PD does in small babies. Creatinine clearance will be measured twice daily throughout the 4 days of the study by comparing the creatinine concentrations measured in blood samples taken for clinical reasons with the concentrations in waste dialysis fluid taken at the same time.

The log10 geometric mean of the clearances on HD will be subtracted from the equivalent values on PD, producing a ratio of HD/PD clearances.

Secondary outcome measures
1. Whether the Newcastle HD machine will provide better clearance of the waste chemicals urea and phosphate than PD does in small babies. These clearances will be measured in parallel to the creatinine clearances.
2. Whether the Newcastle HD machine will provide greater and more precise control of fluid removal than PD does in small babies. This will be measured by comparing how closely the volumes removed each day compare to the prescribed clinical target.
3. Whether the Newcastle HD machine will be equally safe, and that it will be less time consuming and more convenient for the nursing staff to operate than PD. These will be assessed by recording all possible adverse events, and by a questionnaire to the medical and nursing staff on convenience of use and user preference.

Overall study start date
01/01/2012

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Being treated in Freeman Hospital Paediatric Intensive Care Unit
2. Weighing ≤8 kg
3. Being judged by the consultants in the clinical teams responsible for their care to require either dialysis or ultrafiltration, or both. This decision may be made on biochemical or other pathophysiological criteria, which will be documented.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Up to 16, in 2 blocks of 8, which will be balanced for cases starting on PD or HD.

Key exclusion criteria
Having an incomplete abdominal wall or recent abdominal surgery which would render PD impossible. These babies will be treated with the Newcastle infant HD machine on humanitarian grounds, but will not form part of the formal study.
There will be no need to add extra grounds for non-inclusion, such as their survival chances or other co-morbidities. This is because the exclusion criteria already applied by the requesting medical team will have already have ruled out clinically inappropriate cases. These include a thorough holistic assessment of all babies for whom open-heart surgery is considered, and multidisciplinary discussions before additional therapies such as post-operative dialysis are requested.

Date of first enrolment
01/01/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Newcastle
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne University Hospital NHS Foundation Trust (UK)

Sponsor details

c/o Ms Amanda Tortice (Head, Joint Research Office)
Joint Research Office
Royal Victoria Hospital
Queen Victoria Road
Newcastle
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Newcastle Healthcare Charity (UK)

Funder Name
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2014		Yes	No