

Myocardial stunning during paediatric dialysis and the effects of cooling the dialystate during haemodialysis

Submission date

29/04/2010

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

29/04/2010

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

12/04/2017

Condition category

Urological and Genital Diseases

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

5119

Study information

Scientific Title

Myocardial stunning during paediatric dialysis and the effects of cooling the dialysate during haemodialysis: a randomised interventional treatment trial

Study objectives

Original hypotheses:

In comparison to standard 37°C dialysate, dialysate temperature 0.5°C below core body temperature reduces:

1. HD-induced regional LV dysfunction (myocardial stunning)
2. The incidence of IDH and therefore improves the potential for fluid removal during HD (UF)
3. The side effects of IDH and therefore improves the dialysis experience for the child
4. Circulating surrogate markers of myocardial injury

Aim of this pilot:

Primary aim was to determine whether using dialysate 0.5°C cooler than body temperature is associated with a decrease in acute left ventricular (LV) dysfunction as measured by 2D speckle tracking within limits of patient tolerability of feeling cold.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Research Ethics Service, Central London REC 2, 31/07/2007, ref: 07/Q0508/64

Study design

Randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled 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

Topic: Renal and Urogenital; Subtopic: Renal and Urogenital (all Subtopics); Disease: Renal

Interventions

The patient will be randomised to cooled dialysate or dialysate temperature of 37°C.

Follow-up length: 24 months

Study entry: single randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Regional LV dysfunction; patients will undergo echocardiogram assessments at 0, 15 and 240 minutes post-dialysis

Secondary outcome measures

To determine the differences between cooled and standard dialysate in the:

1. Incidence of hypotensive episodes (IDH) defined as a blood pressure (BP) below the 5th percentile adjusted for age and sex
2. Incidence of self-reported intradialytic and postdialytic symptoms
3. Quality of the dialysis procedure based on a specific questionnaire designed to assess their treatment experience and symptoms related to feeling cold during dialysis
4. UF achieved, calculated as the ratio of actual UF volume and desired UF volume

Overall study start date

01/12/2007

Completion date

01/07/2011

Eligibility**Key inclusion criteria**

1. Children on conventional 4 hours three times/week dialysis
2. Stable on dialysis for 2 months
3. Male and female, lower age limit of 1 month

Participant type(s)

Patient

Age group

Child

Lower age limit

1 Months

Sex

Both

Target number of participants

Planned Sample Size: 40

Key exclusion criteria

Difficult echocardiogram assessments

Date of first enrolment

01/12/2007

Date of final enrolment

01/07/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

30 Guilford Street

London

United Kingdom

WC1N 1EH

Sponsor information

Organisation

Great Ormond Street Hospital for Children (UK)

Sponsor details

Department of Paediatric Oncology

Great Ormond Street

London

England

United Kingdom

WC1N 3JH

Sponsor type

Hospital/treatment centre

Website

<http://www.ich.ucl.ac.uk/>

ROR

<https://ror.org/03zydm450>

Funder(s)

Funder type

Charity

Funder Name

Kids Kidney Research (UK)

Alternative Name(s)

KKR

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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