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

Submission date	Recruitment status	[ ] Prospectively registered
29/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/04/2017	Urological and Genital Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
5119

Study information

Scientific Title
Myocardial stunning during paediatric dialysis and the effects of cooling the dialystate 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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 months

Sex
All

Key exclusion criteria
Difficult echocardiogram assessments

Date of first enrolment
01/12/2007

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

30 Guilford Street
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
Great Ormond Street Hospital for Children (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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes