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The Hypertension Optimal Treatment in Children with Chronic Kidney Disease study

Submission date	Recruitment status	[_] Prospectively registered
16/08/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/08/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/04/2025	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys do not work effectively. With modern treatments and advancements in dialysis, increasing numbers of children with CKD are surviving through childhood and early adulthood. Thereafter, however, heart disease becomes one of the major causes of death in these young adults. Restoring kidney function by transplantation reduces but does not eliminate this increased risk and arterial disease (narrowing of the arteries) in these adults is likely to relate to preclinical disease developing during childhood. In adult patients with CKD lowering blood pressure has been found to have a beneficial effect on both heart and kidney outcomes, with suitable recommendations from expert groups and international committees. Recommendations for children with CKD differ, with current recommendations to maintain blood pressure within the normal range for the child' s age, gender and height. The aim of this study is to determine the relationship between left ventricular mass and hypertrophy (increase in size of the left side of the heart), arterial function and structure with the severity and duration of childhood CKD, and to examine the relationship of these measures to blood pressure. We will also determine whether aggressive blood pressure reduction is effective at normalising left ventricular hypertrophy, arterial function and structure.

Who can participate?
CKD patients aged 2 to 15 years, and children with normal kidney function and blood pressure attending hospital for an unrelated medical review or the siblings of patients with CKD.

What does the study involve?
CKD patients are randomly allocated to either aggressive blood pressure reduction or standard care (maintain blood pressure within the normal range). The differences in left ventricular mass and arterial function and structure are measured after 2 and 4 years.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
St Thomas's Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2012 to July 2017

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Dr Manish Sinha
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12925

Study information

Scientific Title
The Hypertension Optimal Treatment in Children with Chronic Kidney Disease study: the HOT-KID study - a randomised trial to compare effects of aggressive versus standard targets in blood pressure on target organ damage in children with CKD

Acronym
HOT-KID

Study objectives

The aim of this project is to:
1. Determine the association of left ventricular mass and hypertrophy (LVH), arterial function and structure with severity and duration of childhood CKD and to examine the relation of these measures to blood pressure
2. Perform a randomised controlled trial to determine whether aggressive blood pressure reduction (below 40th percentile) compared to standard care (between 50th-75th percentile) is effective in normalising left ventricular hypertrophy, arterial function and structure, improves urinary protein excretion
3. Establish a cohort of children with CKD to be followed prospectively to determine predictors of progression of CKD, subclinical and clinical cardiovascular disease.

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12925

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 10/H0802/13

Study design
Randomized interventional 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
Description: 150 subjects for randomisation and n=150 age matched controls
Blood pressure control, Control of clinic systolic blood pressure to target using ACEi therapy as first line agent. Followed up at 5 months

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
The differences in LV mass between aggressive and standard treatment groups measured at 2 and 4 years

Secondary outcome measures
Differences in cIMT and PWV measured at 2 and 4 years

Overall study start date
08/08/2012

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Aged 2 to 15 years
2. Chronic kidney disease with eGFR between 15-90 ml/min/1.73m2 for two consecutive measurements in the last 12 months
3. With or without anti-hypertensive/s medications (irrespective of recent change/s in antihypertensive therapy)
4. Subjects with average clinic systolic BP <50th percentile and on no antihypertensive medication will be eligible as CONTROL subjects only
5. Other CONTROL subjects will include children with normal renal function and blood pressure attending hospital for unrelated medical review or siblings of subjects with CKD
6. Male and female participants

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
UK Sample Size: 300

Total final enrolment
124

Key exclusion criteria
1. Age <2 and >15 years
2. Subjects who have/had an arterio-venous fistulae
3. Subjects who have/had are on dialysis
4. Subjects who have/had a functioning kidney transplant
5. Patients with symptomatic BP or with past history of difficulty to control BP or
6. Patients in whom there is a clinical urgency to treat BP and inclusion in study may result inpossible delay of treatment
7. Patients with arrhythmia or clinical heart failure
8. Patients with known structural cardiac abnormality
9. Subjects on treatment with angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) agents for treatment of proteinuria only or
10. Subjects who are likely to be of clinical concern following up or down titration of BP levels as described in Appendix 3
11. Subjects who are unable or intolerant to performance of study measurements e.g. height, echo or PWV
12. Subjects who have/had intolerance to Angiotensin converting enzyme inhibitors (ACEi) drug /s or have any existing contraindications

Date of first enrolment
08/08/2012

Date of final enrolment
24/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas's Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St. Thomas' NHS Foundation Trust (UK)

Sponsor details

Thomas Guy House
Lambeth Palace Road
London
England
United Kingdom
SE1 7EH

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		25/11/2022	29/11/2022	Yes	No
Other publications		21/04/2025	24/04/2025	Yes	No