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Determining reference values for renal biomarkers in healthy children

Submission date	Recruitment status	[_] Prospectively registered
22/02/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/04/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/03/2017	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Some children who are unwell can have damage caused to their kidneys either by the illness itself, or the drugs used to treat the illness. Currently we measure a substance called creatinine in blood tests to check how well the kidneys are working. However, creatinine is slow to show any damage to the kidney, so we may not find out that damage has occurred until it is too late to reverse it. Also doing this test means having to take a blood sample. A number of substances, which we call biomarkers, can be measured in the urine. We think that some of these biomarkers might be useful at telling us how well a childs kidneys are working, and whether any damage is occurring.
This study will help us to develop urine biomarker tests that will one day be part of our normal clinical practice, and will improve our care of future children.

Who can participate?
We are asking healthy children aged 0 to 16 years to consider taking part in this study.

What does the study involve?
The study has two parts. Participants can do just the first part, or they can do both parts. Children, and their parents, will be approached for recruitment in a number of different settings: in schools, nurseries, at Alder Hey Childrens Hospital (AHCH) in Liverpool, and children of University of Liverpool or AHCH employees.
Part 1
A single urine sample will be collected from the child. Ideally the urine sample will be collected by asking the child to pass urine into a sterile container.
Part 2
This part will take longer, and will need the child to do four more urine samples at home. They will need to collect:
A morning urine sample once a week for the next three weeks.
One bedtime urine sample the evening before one of the morning urine samples.
The morning samples should be done when the child gets up, and the evening sample just before going to bed. The evening sample will need to be kept in the fridge overnight. The child & their parents will be given sample pots to take home. The sample will need to be brought on the morning of collection to the research team at the site of recruitment.

We will store the urine samples in a freezer, and test for different biomarkers at different times. We will keep the sample until it is used up.

What are the possible benefits and risks of participating?
We do not anticipate any problems. We will choose an appropriate urine collection method for each child. There are no immediate benefits.
If we find the urine biomarkers are too high in a childs urine sample we will check this again in our laboratory. If it is still high we will ask the childs general practitioner (GP) to see them.

Where is the study run from?
This research is being run by the University of Liverpool and Alder Hey Childrens NHS Foundation Trust.

When is study starting and how long is it expected to run for?
The study started in March 2012, and is expected to run until October 2014

Who is funding the study?
The study is funded by the Medical Research Council.

Who is the main contact?
Dr Steve McWilliam
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11810

Study information

Scientific Title
DEtermining Reference Values for renal biomarkers in healthy children

Acronym
DERiVe

Study objectives
Some children who are unwell can have damage caused to their kidneys either by the illness itself, or the drugs used to treat the illness. Currently we measure a substance called creatinine in blood tests to check how well the kidneys are working. However, creatinine is slow to respond to any damage to the kidney, so we may not find out that damage has occurred until it is too late to reverse it. Also doing this test means having to take a blood sample.

A number of substances, which we call biomarkers, can be measured in the urine. We think that some of these biomarkers might be useful at telling us how well a childs kidneys are working, and whether any damage is occurring.

We need to measure these biomarkers in the urine of normal healthy children so that we know what their normal level is. This will help us when we start measuring the biomarkers in unwell children as we will be able to see any differences. This study will help us to develop urine biomarker tests that will one day be part of our normal clinical practice, and will improve our care of future children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West Liverpool East, 25th January 2012, ref:12/NW/0060

Study design
Observational study

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Screening

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
Kidney function

Interventions
In this study healthy children will be asked to provide a single urine sample. In addition, some will provide four further urine samples over the following 3 weeks (3 morning samples and one evening sample). These urine samples will be analysed for a number of urine biomarkers. The aim of the study is to produce reference values for urine biomarkers in healthy children, to assess variation between individuals, and within the same subject with time of day or over a period of weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Measured urinary biomarker values

Secondary outcome measures
1. The variation in measured urinary biomarker values between subjects
2. The variation in biomarker values within subjects depending on the time of day, or over a period of weeks

Overall study start date
01/03/2012

Completion date
01/10/2014

Eligibility

Key inclusion criteria
Male or female, age 0-16 years

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria
1. Current febrile illness
2. History of any kidney problem or urinary tract infections
3. Current medications known to cause renal problems (especially nonsteroidal antiinflammatory drugs such as ibuprofen)
4. Diagnosis of cystic fibrosis (by sweat test or genotype)
5. History of exposure to aminoglycoside antibiotics within the last 3 months

Date of first enrolment
01/03/2012

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Molecular and Clinical Pharmacology
Liverpool
United Kingdom
L69 3GL

Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
UK Medicines for Children Research Network Coordinating Centre
Liverpool
England
United Kingdom
L12 2AP

Sponsor type
University/education

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (G1000417. ID number 94909)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2014

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	01/02/2014		Yes	No