

Determining reference values for renal biomarkers in healthy children

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

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 child's 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 Children's 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 child's urine sample we will check this again in our laboratory. If it is still high we will ask the child's 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 Children's 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

S.Mcwilliam1@liverpool.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Stephen J McWilliam

Contact details

Molecular and Clinical Pharmacology

1-3 Brownlow Street

Liverpool

United Kingdom

L69 3GL

+44 151 795 5407

S.Mcwilliam1@liverpool.ac.uk

Additional identifiers

Protocol serial number

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 child's 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

Study type(s)

Screening

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(s)

Measured urinary biomarker values

Key secondary outcome(s)

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

Completion date

01/10/2014

Eligibility**Key inclusion criteria**

Male or female, age 0-16 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

16 years

Sex

All

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**

United Kingdom

England

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

Sponsor information

Organisation
University of Liverpool (UK)

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
Results article	results	01/02/2014		Yes	No