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The Quick Wee method of inducing faster clean catch urine sample collection in pre-continent infants

Submission date
25/03/2020

Recruitment status
No longer recruiting

Registration date
31/03/2020

Overall study status
Completed

Last Edited
22/11/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Urine is a waste product produced by the kidneys, so testing it can show if the kidneys are not working well. For instance, if there is protein in the urine sample, the kidneys may not be filtering it out well. If there is sugar in the urine sample, this might be an indicator that sugar levels in the blood are too high. If your child has a urine infection, the bacteria may be present in the urine sample. Testing a urine sample is usually the first stage in carrying out a general assessment, before blood tests are needed.
The process of obtaining a clean catch urine sample from pre-continent infants without the use of invasive strategies can be difficult and time consuming for clinicians. However, the invasive methods are not well received by parents and require staff with the ability to perform such methods on young babies.
The use of bladder stimulation techniques to obtain samples in a timelier manner have recently been studied. One such method, the Quick Wee method has been shown in one randomized control trial in a tertiary paediatric emergency department to lead to quicker sample collection. The quick wee method involves rubbing cold saline onto the abdomen of infants to attempt to prompt urination and collect a sample that is not contaminated.

Who can participate?
Infants between 1 month and 12 months old.

What does the study involve?
After parental consent is obtained babies are randomised to either the intervention arm (quick wee method during clean catch collection) or control arm (usual care clean catch urine collection). This involves preparing the baby for urine sampling by clean catch method and performing either the control or intervention for the five minute study time.

What are the possible benefits and risks of participating?
The benefits of participation are the potential for a quicker sample collection in the control arm,

as well as adding to the evidence base for this method. Infants in the control arm have usual care performed so there are no added risks in this group. The potential risk to the intervention group is the possibility of discomfort to the infant due to the cold saline stimulation.

Where is the study run from?
Mayo University Hospital (Ireland)

When is the study starting and how long is it expected to run for?
February 2019 to July 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Aoife Branagan, Branagaa@tcd.ie

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Does the Quick Wee method induce faster urination for the collection of clean catch urine samples in pre-continent infants when compared with standard clean catch urine collection?

Study objectives
The use of cold fluid applied to the supra-pubic area in infants will induce urination. This can be used to induce urination for collection of sterile samples for testing in the diagnosis of urinary tract infection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/11/2018, Research Ethics committee, Mayo University Hospital (Castlebar, Co. Mayo, Ireland; +353 (0)94 9042000; no email provided), ref: TOM/DP

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Urinary tract infection

Interventions
Randomisation was done by random permuted blocks of 8 using shuffling of sealed opaque envelopes.

The intervention arm of this study was the Quick Wee method - rubbing of cold saline to the supra-pubic area.

The control arm was standard method of collection for clean catch urine samples.

All infants were prepared for collection of a clean catch urine sample and all necessary equipment was prepared to carry out the quick wee method. The envelope containing the group assignment was opened at the bedside immediately prior to the opening of the nappy.

In the intervention group, infants underwent cleaning of the perineum for ten seconds with room temperature sterile water and then had cold saline rubbed to the supra-pubic area up to five minutes study time.

In the usual care arm, after initial cleaning the clinician waited up to five minutes to see if the infant would spontaneously void.

The duration of the treatment in both groups was 5 minutes – either with cold saline stimulation or no stimulation with a clinician waiting to catch a sample if the baby voided.

There was no follow-up of infants after the study period described above, however, the results of any samples obtained which were sent for culture were followed.

Intervention Type
Procedure/Surgery

Primary outcome measure
Void or no void measured during the 5 minute study period

Secondary outcome measures
1. Time to void (seconds) measured using stopwatch during the 5 minute study period
2. Contamination measured using screening dipstick at the time of data collection, and number of white cells on microscopy and any growth on culture
3. Parental and clinician satisfaction measured using a 5-point Likert scale (Very satisfied, Satisfied, Neutral, Unsatisfied, Very unsatisfied) at the end of the 5 minute study period

Overall study start date
01/10/2018

Completion date
30/07/2019

Eligibility

Key inclusion criteria
Infants between 1 month and 12 months of age

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Months

Upper age limit
12 Months

Sex
Both

Target number of participants
130

Total final enrolment
140

Key exclusion criteria
1. Anatomical or neurological abnormality affecting voiding
2. Clinician decision that participation would delay necessary care

Date of first enrolment
01/02/2019

Date of final enrolment
20/07/2019

Locations

Countries of recruitment
Ireland

Study participating centre
Mayo University Hospital
Castlebar
Mayo
Ireland
-

Sponsor information

Organisation
Mayo General Hospital

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Sponsor type
Hospital/treatment centre

Website
http://www.mayokaset.com/en/

ROR
https://ror.org/02z8t9146

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Data stored as excel spreadsheet, data is now available. Requests for data will be looked at on case by case basis. Analysis was by intention to treat. Written consent was obtained from parents. Data is anonymised, patients are identified by study number only.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/11/2021	22/11/2021	Yes	No