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Randomised trial of a vibrating bladder stimulator to induce urine flow in acute paediatrics

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
18/01/2008

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0264171565

Study information

Scientific Title

Study objectives
Does use of a vibrating bladder stimulator alter the time taken to pass urine in children?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Urological and Genital Diseases:

Interventions
RCT:
1. Advice
2. Device

The patients will be assigned to one of two groups: the 'advice' and the 'device' groups. The advice group will be given an advice leaflet which has some tips on how to try to stimulate urine flow. The device group will be shown the use of a bladder stimulator. This is a hand-held vibrating disk which is non-painful and has no known side effects. It is pressed on to the lower abdomen and vibrates the bladder, with the aim of stimulating urine flow. The idea behind this stimulator is that the vibrations of the bladder cause a reflex reaction which leads to urine flow.

Half of the patients will be in each group: which group the individuals go in to is decided at random. This is to minimise the possible effects of patients becoming frustrated at perceived preferential treatment within the waiting room area. Full informed consent will be obtained.

The parents would be given a clock and asked to write down when the urine is passed. If a sample is passed and is missed by the parents, this still counts as a time to pass urine. A questionnaire is also given which will ask some questions on the child and their illness, as well as how they think the child coped with the urine collection process.

This is then the end of the study and there will be no further input for the child or their parents.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Time to pass urine from taking the nappy off to urine flow.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2005

Completion date
01/03/2006

Eligibility

Key inclusion criteria
All children to give a urine sample who are not continent of urine (by day or night) attending to the Paediatric Emergency Department at the Bristol Children's Hospital will be asked to take part.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
97

Key exclusion criteria

1. Children too unwell, in the opinion of the doctor treating
2. Those who do not need a clean sample of urine (so could have a urine bag)
3. Those who in the opinion of the consent taker, have insufficient understanding (due to language or other factors) of the trial process
4. Those who do not have a legal guardian with them
5. Those who have abnormalities in their anatomy or nerves which affect their ability to pass urine

Date of first enrolment
01/09/2005

Date of final enrolment
01/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
C/O Research and Effectiveness Department
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
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Sponsor type
Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
United Bristol Healthcare NHS Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/05/2008		Yes	No