ISRCTN50938901 https://doi.org/10.1186/ISRCTN50938901

How painful is a urethral swab?

Submission date 27/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/01/2010	**Overall study status** Completed	
Last Edited 04/07/2011	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ade Apoola

Contact details
Derby Hospitals NHS Foundation Trust
London Road Community Hospital
Genito-Urinary Department
London Road
Derby
United Kingdom
DE1 2QY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RD-5103-012-07

Study information

Scientific Title

How painful is a urethral swab? A single centre, randomised controlled trial.

Study objectives
To investigate the intensity of the discomfort felt during the insertion of the first urethral swab, when different swab types are used.

1. To determine if there is any difference in the discomfort felt during the insertion of the first of three urethral swabs using different types.
2. To investigate the intensity of the discomfort felt during the insertion of the second and the third urethral swab using different types.
3. To determine if there is an association between particular healthcare workers (HCW) and the discomfort experienced during a urethral swab procedure.
4. To assess if previous experience of swab taking in the patient has an effect on the perception of discomfort felt during the procedure.
5. To assess if urethral inflammation affects the discomfort felt during the procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Derbyshire Research Ethics Committee (REC) approved on the 3rd of March 2008 (ref: 07/H0401 /158)

Study design
Single centre randomised 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Genito-urinary medicine

Interventions
Following informed consent, participants will be randomised to receive one of the following types of swab first:
1. To have a gonorrhoea Dacron tipped swab first
2. To have a chlamydia Rayon tipped swab first
3. To have a plastic urethral loop swab first

All patients will have the other 2 types of swab taken as routine practice in an order pre-specified by the pre-randomised envelopes.
Participants will be given a short questionnaire to complete before the first swab is taken for investigations.
Participants will be given a numerical rating scale to measure intensity of discomfort felt after each of the 3 swabs have been taken.
All three swabs are routinely taken in clinics in accordance with manufacturers instructions.
The duration of the study will be 6 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The discomfort felt during urethral swab procedure after the first of 3 different swab types are used, will be assessed using the Visual Analogue Scale (0-100mm)

Secondary outcome measures
1. The discomfort during the procedure using each of the other two types of swab using the Visual Analogue Scale (0-100mm) will be assessed.
2. Data on presence and severity of urethral symptoms prior to swab taking will be collected using the Data Collection form.
3. Data will also be collected on the identity of the HCW taking the swab and the presence of epithelial cells (a marker of an adequately taken swab) and polymorphonuclear cells (a marker of inflammation) in the specimen and voided urine after swabs.

Overall study start date
19/05/2008

Completion date
19/11/2008

Eligibility

Key inclusion criteria
All male patients over 16 attending the Genito-Urinary clinic during the study period and having swab tests will be invited to participate in the study.

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
121

Key exclusion criteria
1. Subjects who have passed urine within 2 hours of planned procedure (swab)
2. Subjects who have taken analgesics, anti-depressants or anti-epileptic drugs in the previous 24 hours

Date of first enrolment
19/05/2008

Date of final enrolment
19/11/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby
United Kingdom
DE1 2QY

Sponsor information

Organisation
Derby Hospitals NHS Foundation Trust (UK)

Sponsor details
Royal Derby Hospital
Uttoxeter Road
Derby
England
United Kingdom
DE22 3NE
+44 (0)1332 340131
teresa.grieve@derbyhospitals.nhs.uk

Sponsor type
Hospital/treatment centre

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Derby Hospitals NHS Foundation Trust (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	01/03/2011		Yes	No