ISRCTN13804526 https://doi.org/10.1186/ISRCTN13804526

A randomised controlled trial to assess the efficacy and acceptability of non-invasive testing sexually transmitted infections in asymptomatic patients within a GUM setting

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
30/05/2012

Condition category
Infections and Infestations

[_] 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

Protocol serial number
N0233179831

Study information

Scientific Title

Study objectives
The study will assess and compare the acceptability by patients of non-invasive screening for sexually transmitted infections with current procedures and standards of care. These will be asymptomatic low risk patients within a GUM clinic setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 20/07/09: ethics approval granted by Solihull LREC date: 7th March 2006 REC ref: 05 /Q2706/105.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Infections and Infestations: Sexually transmitted diseases

Interventions
Patients will book in the normal way, then a nurse will approach with the patient information sheet. A sexual history will be taken. The standard group will be tested in the standard way, the non-invasive will have urine samples. A patient questionnaire will asses satisfaction at treatment.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Acceptability of the non-invasive testing procedures as compared with the current standard of care.

Key secondary outcome(s))
Patient time spent in the clinic (consultation time and total visit time), detection of STI in both study and control group and consultation costs.

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. Asymptomatic heterosexual men
2. Asymptomatic hetrosexual women who have not had receptive anal intercourse within the last 3 years
3. Asymptomatic homosexual/ bisexual men who have not had receptive anal intercourse within the last 3 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Contacts of an sexually transmitted infection (STI)
2. Pregnancy
3. Symptomatic patient

Date of first enrolment
14/03/2006

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of GU Medicine
Birmingham
United Kingdom
B4 6DH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
R&D for Birmingham and Solihull Consortium (UK)

Funder Name
Heart of Birmingham Teaching Primary Care Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

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	01/12/2010		Yes	No