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	Recruitment status No longer recruiting	Prospectively registered		
28/09/2007		Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
28/09/2007		[X] Results		
Last Edited 30/05/2012	Condition category Infections and Infestations	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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: 05/02706/105.

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	l Peer reviewed?	Patient-facing?
Results article	results	01/12/2010	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	i No	Yes