

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

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 30/05/2012	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English Summary

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Jonathan Ross

### Contact details

Department of GU Medicine  
Whittall Street Clinic  
Whittall Street  
Birmingham  
United Kingdom  
B4 6DH

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0233179831

## Study information

### Scientific Title

### Study hypothesis

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Screening

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Condition

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 assess satisfaction at treatment.

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

Acceptability of the non-invasive testing procedures as compared with the current standard of care.

**Secondary outcome measures**

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

**Overall study start date**

14/03/2006

**Overall study end date**

31/03/2007

## Eligibility

**Participant inclusion criteria**

1. Asymptomatic heterosexual men
2. Asymptomatic heterosexual 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

**Age group**

Not Specified

**Sex**

Both

**Target number of participants**

Added 20/07/09: trial aimed to recruit about 400 participants and managed 391.

**Participant exclusion criteria**

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

**Recruitment start date**

14/03/2006

**Recruitment end date**

31/03/2007

## Locations

**Countries of recruitment**

England

United Kingdom

**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

**Sponsor details**

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

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

## **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

**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?
<a href="#">Results article</a>	results	01/12/2010		Yes	No