# 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	<ul><li>Prospectively registered</li></ul>		
		☐ Protocol		
Registration date 28/09/2007	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 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

**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

# 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

## 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

## 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**

### 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

#### 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

#### Age group

**Not Specified** 

#### Sex

Both

# Target number of participants

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

# 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

England

**United Kingdom** 

Study participating centre
Department of GU Medicine
Birmingham

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?
Results article	results	01/12/2010		Yes	No