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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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

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
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