ISRCTN42867448 https://doi.org/10.1186/ISRCTN42867448

Self-taken vaginal swabs and gonorrhoea detection

Submission date	Recruitment status	[_] Prospectively registered
24/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/08/2014	Infections and Infestations	

Plain English Summary
Background and study aims
Chlamydia and gonorrhoea are common sexually transmitted infections (STIs) in the UK. Infected women often have no symptoms, but without treatment they can become infertile. Finding these unrecognised infections is therefore important. For gonorrhoea, the standard test is to attempt to grow the bacteria in a laboratory. An instrument called a speculum is gently inserted into the vagina to hold the walls of the vagina open so that the neck of the womb is visible. A small brush-like instrument will be used to take some cells from the neck of the womb. Special storage and transport are needed to ensure the samples arrive promptly and safely at the laboratory.
The nucleic acid amplification test (NAAT) method, currently used to detect chlamydia, is now able to detect gonorrhoea on the same sample. It is a test that can be done on non–invasive samples i.e. urine and self–taken vaginal swabs.
Women prefer these tests and special storage or transport arrangements are not needed. If the NAATs gonorrhoea test was as good as the current standard gonorrhea test, women with no symptoms could be tested for both chlamydia and gonorrhoea without needing to have an examination. We therefore plan to compare the NAATs gonorrhoea test with the standard gonorrhoea test. The NAATs test we plan to use is FDA cleared and CE Marked for use on all the swabs we plan to take.

Who can participate?
Women attending our clinic for STI tests.

What does the study involve?
We will invite women attending our clinic for STI tests to do a self–taken vaginal swab in addition to the standard tests we perform when we examine them. Performing a self–taken vaginal swab has no side effects and has previously been found to be easy and acceptable. We will then be able to evaluate the effectiveness of the self–taken vaginal swab for detecting gonorrhoea in comparison with the standard cultures.

What are the possible benefits and risks of participating?
The possible benefits are that you will be having an additional sample taken for gonorrhoea and chlamydia testing and it is known that the more samples that are performed, the better the

detection rate of any infection that is present. There are no known risks of participating in the study.

Where is the study run from?
The study is taking place at the Centre for Sexual Health at the Leeds General Infirmary.

When is the study starting and how long is it expected to run for?
The study will be starting in early 2009 and is expected to run for up to one year.

Who is funding the study?
The extra swabs and tests will be funded by Gen–Probe, who are the manufacturers.

Who is the main contact?
The main contact for the study is Dr Janet Wilson at the Centre for Sexual Health at the Leeds General Infirmary.

Contact information

Type(s)
Scientific

Contact name
Dr Janet Wilson

Contact details
Department of Genito-Urinary Medicine
Sunnybank Wing
Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7293

Study information

Scientific Title
Comparison of self-taken vaginal swabs versus clinician taken urethral and endocervical swabs for the detection of gonorrhoea using the Gen-Probe Aptima Combo 2 assay

Study hypothesis

This is a prospective cohort study to compare self-taken vaginal swabs for the detection of gonorrhoea using the Gen-Probe Aptima Combo 2 assay versus clinician taken urethral and endocervical swabs for the detection of gonorrhoea by standard culture. Furthermore, we will assess the cost effectiveness of the different methods of detecting gonorrhoea.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds (East) Research Ethics Committee approved on the 3rd February 2009 (ref: 09/H1306/4)

Study design
Single centre randomised interventional screening 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
Topic: Infection; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

Interventions
A self taken vulvo-vaginal swab analysed for gonorrhoea by the Aptima Combo 2 assay, followed by clinician taken urethral and endocervical samples analysed for gonorrhoea by culture then an endocervical sample analysed for gonorrhoea by the Aptima Combo 2 assay. All positive Aptima Combo 2 assays for gonorrhoea will be confirmed using the Aptima GC assay.

The cost of each procedure will be assessed including the cost of the test and staff time.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Sensitivity, specificity, positive and negative predictive values of the Gen-Probe Aptima Combo 2 assay for the detection of gonorrhoea using self-taken vaginal swabs compared with clinician taken urethral and endocervical swabs for the detection of gonorrhoea by standard culture.

Secondary outcome measures
Sensitivity, specificity, positive and negative predictive values of self-taken vaginal swabs compared with clinician taken endocervical swabs for the detection of gonorrhoea using the Gen-Probe Aptima Combo 2 assay.

Overall study start date
01/03/2009

Overall study end date
31/01/2010

Eligibility

Participant inclusion criteria
1. Women aged 16 years and over
2. Presenting for a new or re-registration visit
3. Wish to be tested for both chlamydia and gonorrhoea
4. Give consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
Planned sample size: 4000

Participant exclusion criteria
1. Women who are unwilling or unable to give verbal consent
2. Women who have taken antibiotics in the previous 28 days

Recruitment start date
01/03/2009

Recruitment end date
31/01/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Genito-Urinary Medicine
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust (UK)

Sponsor details
Research and Development Department
34 Hyde Terrace
Leeds
England
United Kingdom
LS2 9LN

Sponsor type
Hospital/treatment centre

Website
http://www.leedsteachinghospitals.com/

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Industry

Funder Name
Gen-Probe Inc. (USA)

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	12/12/2012		Yes	No
Results article	results	01/09/2014		Yes	No