ISRCTN16307168 https://doi.org/10.1186/ISRCTN16307168

# GONDOLA: Gonorrhoea detection using laboratory assessment

**Submission date**
03/02/2020

**Recruitment status**
No longer recruiting

**Registration date**
05/03/2020

**Overall study status**
Completed

**Last Edited**
05/03/2020

**Condition category**
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
Gonorrhoea is a sexually transmitted infection (STI) caused by bacteria called Neisseria gonorrhoeae or gonococcus.
The incidence of gonorrhoea is potentially underestimated because it is not always detected. Undetected or inadequately treated gonorrhoea can cause serious reproductive health consequences and poses a threat to public health due to the emergence of drug-resistant strains; timely and accurate diagnosis is therefore essential. Despite high specificity tests available, N. gonorrhoeae bacteria are technically difficult to preserve and recover from clinical specimens. Any delay in processing, transport and incubation of direct culture plates can significantly reduce the sensitivity of the test, resulting in false negative results and non-treatment. Novel swab transport systems have become increasingly important due their low cost, ease of use and the ability to maintain viability for aerobic, anaerobic and fastidious microorganisms – such as N. gonorrhoeae – over extended times. This may have benefits in clinic settings across the UK, particularly in rural settings where transport times to laboratories may be longer. This study aims to assess the performance of a novel swab incubation and transport system – BioMed's InTray™ GC – compared to the current method of plating onto a solid growth medium to prepare, transport and detect Neisseria gonorrhoeae in sexual health clinics. Further the objective is to assess the potential cost-effectiveness and benefits in terms of storage, transport and incubation time.

Who can participate?
Patients presenting to sexual health clinic with symptom(s) of Neisseria gonorrhoeae infection, presence of urethral or vaginal discharge and/or dysuria, or patients with recent medical history and risk factors that in the opinion of the treating clinician warrants investigation for N. gonorrhoeae infection.

What does the study involve?
Participants will be asked to provide a swab sample (vaginal/cervix/rectal swabs for women and urethral/rectal swabs for men) as per normal practice to test for N Gonorrhoea infection.

What are the possible benefits and risks of participating?
Benefits: There is no guaranteed anticipated clinical benefit from taking part in this study.

However, if the novel Biomed InTray shows significant benefits over the current practice, meaning higher detection rates of gonorrhoea, then the clinical team can use these results for the management of patients. This means that patients may be treated more optimally if the new sample transport kit that is being tested outperforms the current standard transport method. As a result, this study may then also lead to higher quality of gonorrhoea sampling and testing in the future.
Risks: There is no significant increased personal safety risk anticipated for patients who take part in this study. To obtain sufficient material, patients may be swabbed a second time (using a same type of swab they would normally be swabbed with). This may feel a bit uncomfortable for a very brief period of a few seconds.

Where is the study run from?
Cumbria Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2019 to August 2020

Who is funding the study?
Biomed Diagnostics Inc (USA)

Who is the main contact?
Leon Jonker, leon.jonker@nihr.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Leon Jonker

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
261500

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
CPMS 41639, IRAS 261500

# Study information

### Scientific Title
A single-centre, prospective evaluative study to investigate the performance of the Bio Med InTray® GC (a sample collection, transport and culture in-vitro device), compared to current standard methods, to microbiologically detect Neisseria gonorrhoeae

### Acronym
GONDOLA

### Study objectives
To determine the microbiological detection rates of gonorrhoea using InTray™ GC liquid transport medium compared to current practice (agar plating) in Cumbrian sexual health clinics.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 25/04/2019, South East Scotland Research Ethics Committee 01 (Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131 465 5473; Sandra.Wyllie@nhslothian.scot.nhs.uk), ref: 19/SS/0050

### Study design
Non-randomized interventional study

### Primary study design
Interventional

### Study type(s)
Diagnostic

### Health condition(s) or problem(s) studied
Gonococcal infection

### Interventions
Participants will be asked to provide a swab sample (vaginal/cervix/rectal swabs for women and urethral/rectal swabs for men) as per normal practice to test for N gonorrhoeae infection. The samples will be processed using the current standard method (which is to use so-called solid agar incubation plates).

As part of the study, an additional swab sample - from the same location and using the same type of swab - may be taken if the initial swab is insufficient.

The swab(s) are used to inoculate a standard agar plate and a Biomed InTray™ plate, and these will be processed after transport to the microbiology laboratory for diagnostic testing. Thereafter the patient will be cared for in the same matter as they normally would. The results of the tests will be communicated as per normal practice by the clinical team. One difference is

that the results of both the agar plating and Biomed InTray™ system may be used to manage patients, subject to agreement from the microbiologist and sexual health consultant. This means that if the Biomed InTray system performs better than agar plating, more gonorrhoea cases may be detected and treated accordingly.

There are no follow-up visits when patients take part in the study - it is just a single visit (ie the clinic visit that patients already attend).

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
Detection rates of gonococcal infection assessed by microbiology laboratory diagnostic testing

### Key secondary outcome(s))
None

### Completion date
31/08/2020

## Eligibility

### Key inclusion criteria
1. Presenting to sexual health clinic with symptom(s) of Neisseria gonorrhoeae infection, presence of urethral or vaginal discharge and/or dysuria OR
2. Recent medical history and risk factors that in the opinion of the treating clinician warrants investigation for N. gonorrhoeae infection

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Under the age of 18 years
2. Unable to fully understand the consent process and provide informed consent due to either language barriers or mental capacity

### Date of first enrolment
29/04/2019

### Date of final enrolment
31/08/2020

# Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Carleton Clinic**
Cumbria Partnership NHS Foundation Trust
Cumwhinton Road
Carlisle
United Kingdom
CA1 3SX

# Sponsor information

### Organisation
North Cumbria University Hospitals NHS Trust

# Funder(s)

### Funder type
Industry

### Funder Name
Biomed Diagnostics Inc

# Results and Publications

### Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

### IPD sharing plan summary
Other

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |

| | | | | | |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet version v4 | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | | 06/12/2019 | 05/03/2020 | No | No |