

# GONDOLA: Gonorrhoea detection using laboratory assessment

<b>Submission date</b> 03/02/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/03/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/03/2020	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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](mailto:leon.jonker@nihr.ac.uk)

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Leon Jonker

**Contact details**

North Cumbria Integrated Care NHS Foundation Trust

R&D Dept, Carleton Clinic

Carlisle

United Kingdom

CA1 3SX

+44 (0)1228 608926

[leon.jonker@nihr.ac.uk](mailto:leon.jonker@nihr.ac.uk)

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

261500

**ClinicalTrials.gov number**

Nil known

## Secondary identifying numbers

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

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Diagnostic

## 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

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 measure**

Detection rates of gonococcal infection assessed by microbiology laboratory diagnostic testing

### **Secondary outcome measures**

None

### **Overall study start date**

19/03/2019

### **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

### **Age group**

Adult

### **Sex**

Both

**Target number of participants**

Planned Sample Size: 60; UK Sample Size: 60

**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**

England

United Kingdom

**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

**Sponsor details**

(now known as North Cumbria Integrated Care NHS Foundation Trust)

Voreda House

Portland Place

Penrith

Carlisle

England

United Kingdom

CA11 7BF

+44 (0)1228 608926

dave.dagnan@ncic.nhs.uk

**Sponsor type**

Hospital/treatment centre

## Funder(s)

**Funder type**

Industry

**Funder Name**

Biomed Diagnostics Inc

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

31/03/2021

**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?
<a href="#">Protocol file</a>	version v4	06/12/2019	05/03/2020	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No