

Storage, transport and incubation for N. gonorrhoea samples

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| Submission date 03/02/2020 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 11/03/2020 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 07/06/2023 | Condition category 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

The incidence of gonorrhoea is potentially underestimated because of suboptimal processing of samples, diagnosis methodology, case reporting and surveillance. 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. gonorrhoea 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 to their low cost, ease of use and the ability to maintain viability for aerobic, anaerobic and fastidious microorganisms – such as N. gonorrhoea – 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 transport system – Sigma VCM (product code MW911S, marketed by the company MWE) – compared to the current method of plating onto a solid growth medium to prepare, transport and detect Neisseria gonorrhoea in sexual health clinics, and 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 gonorrhoea

What does the study involve?

Participants will be asked to provide a swab sample (vaginal/cervix swabs for women and a urethral sample for men) as per normal practice to test for N. gonorrhoea 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 - will be taken and this will be processed using a tube with liquid in it to transport the sample to the laboratory for diagnostic testing. Thereafter participants will be cared for in the same manner as they normally would. The results of the tests will be communicated as per normal practice by the clinical team. There are no follow-up visits when patients take part in the study - it is just a single visit (i.e. the clinic visit that patients already attend).

What are the possible benefits and risks of participating?

There is no intended clinical benefit from taking part in this study. However, if the novel Sigma VCM 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 a higher quality of gonorrhoea sampling and testing in the future. This is not guaranteed, and that is why the researchers are undertaking this study to determine which transport process for sexual health samples is best. Participants cannot claim payments, reimbursement of expenses or any other benefits or incentives for taking part in this study. There is no significant increased personal safety risk anticipated for participants. To obtain sufficient material, patients may be swabbed a second time (using the 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. Appropriate precautions are in place to ensure that medical and personal information is kept safe.

Where is the study run from?

North Cumbria Integrated Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

December 2018 to May 2020

Who is funding the study?

Medical Wire & Equipment Co. (Bath) Limited

Who is the main contact?

Dr Leon Jonker

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Integrated Research Application System (IRAS)

243037

Study information

Scientific Title

A single-centre, controlled, prospective study to investigate the performance of the novel Sigma VCM diagnostic storage and transport kit compared to current standard methods to detect *Neisseria gonorrhoea*

Acronym

STRINGS

Study objectives

This study aims to assess the performance of a novel swab transport system – Sigma VCM (product code MW911S, marketed by the company MWE) – compared to the current method of plating onto a solid growth medium to prepare, transport and detect *Neisseria gonorrhoea* in sexual health clinics and to assess the potential cost-effectiveness and benefits in terms of storage, transport and incubation time.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 30/10/2018, London - Dulwich Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8241, +44 (0)2071048089; dulwich.rec@hra.nhs.uk), REC ref: 18/LO/1936

Study design

Non-randomised; Interventional; Design type: Diagnosis, Device

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Neisseria gonorrhoea infection

Interventions

If a patient decides to take part in the study, written informed consent will be taken.

Participants will be asked to provide a swab sample (vaginal/cervix swabs for women and a urethral sample for men) as per normal practice to test for *N. gonorrhoea* 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 - will be taken and this will be processed using a tube with liquid in it to transport

the sample to the laboratory for diagnostic testing. Thereafter participants will be cared for in the same manner as they normally would. The results of the tests will be communicated as per normal practice by the clinical team.

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

Intervention Type

Other

Primary outcome(s)

The detection rates of the Sigma VCM compared to current (in)direct agar plating practise in Cumbrian sexual health clinics, measured using NAAT (PCR) at a single study visit

Key secondary outcome(s)

Measured at a single timepoint/study visit:

1. The detection rates of direct or indirect plating versus Sigma VCM, measured using NAAT (PCR) at a single study visit
2. Time between sample taken from patient to arrival in the microbiology department, measured using timing records in patient and laboratory records
3. Storage requirements, measured using feedback from clinical staff
4. Transport requirements, measured using feedback from clinical and laboratory staff
5. Incubation time, measured using laboratory records
6. Costs (including materials), measured using cost utilisation analysis

Completion date

30/05/2020

Eligibility

Key inclusion criteria

1. Presenting to sexual health clinic with symptom(s) of Neisseria gonorrhoea
 - 2.1. Presence of urethral or vaginal discharge and/or dysuria
- OR
- 2.2. Recent medical history and risk factors that in the opinion of the treating clinician warrants investigation for N. gonorrhoea 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

01/12/2018

Date of final enrolment

30/04/2020

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Cumbria Partnership NHS Foundation Trust

Carleton Clinic

Cumwhinton Road

Carlisle

United Kingdom

CA1 3SX

Sponsor information

Organisation

North Cumbria Integrated Care NHS Foundation Trust

ROR

<https://ror.org/003hq9m95>

Funder(s)

Funder type

Industry

Funder Name

Medical Wire & Equipment Co. (Bath) Limited

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study 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 | | | 26/07/2023 | No | No |
| Participant information sheet | version v2 | 01/10/2019 | 11/03/2020 | No | Yes |
| Protocol file | version v2 | 01/03/2019 | 11/03/2020 | No | No |