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Storage, transport and incubation for N. gonorrhoea samples

Submission date	Recruitment status	[_] Prospectively registered
03/02/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/03/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/06/2023	Infections and Infestations	[_] 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 matter 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
Dr Leon Jonker

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
243037

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 40245, 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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet

See additional files

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 matter 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 measure
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

Secondary outcome measures
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

Overall study start date
01/10/2018

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 64; UK Sample Size: 64

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
England

United Kingdom

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

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.ncic.nhs.uk/

ROR
https://ror.org/003hq9m95

Funder(s)

Funder type
Industry

Funder Name
Medical Wire & Equipment Co. (Bath) Limited

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation

Intention to publish date
31/12/2020

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?
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
HRA research summary			26/07/2023	No	No