CHLAMOUR Study - Chlamydia at multiple anatomical sites

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The aim of this study is to determine the optimal anatomical sample site for the evaluation of CT viability by comparing the total CT load (as determined by route NAAT) and viable CT load (by V-PCR) from different anatomical sample sites.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chlamydial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48039

Source
ToetsingOnline

Brief title
CHLAMOUR

Condition

- Chlamydial infectious disorders

Synonym
Chlamydia, Sexually transmitted infection

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chlamydia, Public Health, Sexually transmittable infections, Viability

Outcome measures

Primary outcome

The main endpoint of this study is assessment of the viable CT concentration (viable load) at any of the anatomical sample locations.

Other parameters used in this study as determinants to understand the endpoint are:

-CT detection by commercial NAAT (standard routine care; CT positive Yes/No)

-CT DNA concentration (total CT load)

-CT detection by culture (reference method for viable CT detection; Viable CT Yes/No)

For exploratory descriptive analysis we will investigate associated factors from self-reported questionnaire data (e.g. demographics, sexual behaviour, symptoms, etc.). These questionnaires are completed by patients as part of the standard routine care.

Secondary outcome

Not applicable.

Study description

Background summary

The introduction of nucleic acid amplification tests (NAATs) have revolutionized our ability to diagnose Chlamydia trachomatis (CT). In some cases, however, assessment of CT viability is needed * a feature that has been lost with the expanded use of molecular diagnostic techniques * to gain more insight in the clinical diagnostic impact of NAAT. Recently, alternative methods to assess the CT viability have become available (e.g. viability-PCR; V-PCR) and demonstrated high amounts of dead bacteria in self-collected swab samples (i.e., vaginal and anal swabs). Further research is needed to assess the impact on V-PCR results of anatomical sample sites (i.e., vaginal vs. cervical and anal vs. rectal swabs) which may vary in the amount of viable organisms.

Study objective

The aim of this study is to determine the optimal anatomical sample site for the evaluation of CT viability by comparing the total CT load (as determined by route NAAT) and viable CT load (by V-PCR) from different anatomical sample sites.

Study design

Explorative cross-sectional study. At the treatment visit, CT positive women are asked to undergo a speculum examination (after written informed consent) to obtain clinician-collected cervical and vaginal swab samples. Furthermore, clinician-collected swabs will be collected from alternate anatomical locations (i.e., oral, anal, and the perineum). Additionally, after written informed consent, patients undergo a proctoscopic examination to obtain swab samples from the rectum. Swab samples from each anatomical site will be evaluated for CT positivity by routine NAAT and for the total and viable CT load by V-PCR. For exploratory descriptive analysis we will investigate associated factors from coded self-reported questionnaire data (e.g. demographics, sexual behaviour, symptoms, etc.). These questionnaires are completed by patients as part of the standard routine care.

Study burden and risks

There are no direct benefits for the patients who participate as the results of the swabs are not reported to them individually. They participate altruistically to help science to improve CT control and help inform guideline optimization. The burden for participating patients lies in the discomfort a gynaecological speculum examination and optionally a proctoscopy might entail. These procedures pose minimal risk, rarely cause pain, and are mostly done within 10 minutes, so duration is quite short and therefore acceptable for participating patients although some discomfort is not excluded. These procedures are part of the regular health care procedure in certain conditions (symptomatic patients) but here patients are asked to participate fully

voluntary within a setting they already know (after all they are already an STI clinic patient) and they are familiar with the guiding, comforting and trustworthy STI physicians and nurses. Speculum examination including sample collection will take about 15 minutes. An experienced study clinician will collect 10 swab samples (2 oral, 2 cervical, 2 vaginal, 2 anal, and 2 from the perineum; total 15 minutes). Futhermore, after additional written informed consent, two rectal swabs will be collected by the same experienced study clinician during proctoscopic examination of the rectum which will take about 10 minutes. Patients will participate individually and fully voluntary after reading the patient information about the study and after signing written informed consent. No specific subgroups are targeted in this study other than CT positive women attending the STI clinic. Epidemiologic and laboratory data analysis will be performed on coded data and data will not be traceable to individuals. Results will not be available for the patients. Patients only will benefit indirectly because of potential optimization of future STI patient care and improved CT control. Results from this study might have public health impact.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: women, age 18 years or older, genital or anorectal CT diagnosis, and signed written informed consent.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: concurrently infected with Neisseria gonorrhoea (i.e., having an oral, vaginal or anal infection), previously diagnosed HIV or Syphilis, recent (<1 month) use of any antibiotics with some effect on chlamydia trachomatis (excluding e.g. frequently used metronidazole and nitrofurantoine), and being pregnant.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-03-2019
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL67843.068.18