Monitoring therapy success of Chlamydia trachomatis infections using culture A prospective observational cohort study.

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Primary objective: To demonstrate that Positive Ct NAAT results 7, 21 and 49 days after (considered adequate) treatment of urogenital Ct with azithromycin is due to slow clearance of Ct RNA/DNA remnants (Ct culture negative) and not to therapy…

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

Summary

ID

NL-OMON42309

Source
ToetsingOnline

Brief title
Chlamydia test-of-cure study

Condition

- Bacterial infectious disorders
- Skin and subcutaneous tissue disorders

Synonym
Chlamydia, Chlamydia trachomatis

Research involving
Human

Sponsors and support

Primary sponsor: GGD Amsterdam
Source(s) of monetary or material Support: GGD Amsterdam

Intervention

Keyword: Aptima Combo 2, Chlamydia, Culture, Test-of-cure

Outcome measures

Primary outcome

Primary endpoints: Clearance of Ct infection as determined by Ct culture and

NAAT at days 7, 21 and 49 after treatment.

Secondary outcome

Secondary endpoint: sensitivity of Ct culture when compared to Aptima Combo 2

assay and COBAS® 4800 CT/NG TEST on the day of inclusion. To distinguish

recurrent or persistent infections from new infections by determining if

persistent Ct NAAT and/or culture positive results after treatment are caused

by the same Ct strain.

Study description

Background summary

Clinicians may use a one-time follow-up test, a so-called test-of-cure (TOC), in order to confirm success of treatment of a Chlamydia trachomatis (Ct) infection. The value of a TOC using a nucleic acid amplification test (NAAT) after treatment is subject to discussion, as the presence of Ct-nucleic acids after treatment may be prolonged and intermittent. This applies to both DNA and RNA tests, which can not differentiate between dead or living Chlamydia bacteria. It has been shown that the number of NAAT-positive patients does not reach zero at any time point after considered adequate treatment and starts increasing before day 51 after treatment. It is unknown whether this is due to failure of therapy, re-infections or other reasons. Despite the lower sensitivity compared to NAAT, a positive culture (after treatment) can exclude

false positive molecular remnants of successfully treated infections and prove a persistent infection or re-infection with Ct.

Study objective

Primary objective: To demonstrate that Positive Ct NAAT results 7, 21 and 49 days after (considered adequate) treatment of urogenital Ct with azithromycin is due to slow clearance of Ct RNA/DNA remnants (Ct culture negative) and not to therapy resistant viable Ct (Ct culture positive).

Secondary objectives: 1) To estimate the sensitivity of Ct culture in a head-to-head comparison with the Aptima Combo 2 assay and the COBAS® 4800 CT/NG Test in urogenital samples from untreated patients. 2) To distinguish recurrent or persistent infections from new infections by determining if persistent Ct NAAT and/or culture positive results after treatment are caused by the same Ct strain defined by a high resolution multilocus sequence typing method (CT-MLST). 3) To collect data and samples that can be used subsequently for the evaluation of more practical TOC that do not require culture.

Study design

A prospective observational cohort study involving female STI Outpatient Clinic patients with a urogenital Ct infection, objectified by routine Ct NAAT (Aptima Combo 2 assay). Upon consent, participants are asked to complete a questionnaire and undergo four extra speculum examinations to obtain a cervical swab for Ct culture and NAAT on days 0 and 7, 21 and 49 days after treatment.

Study burden and risks

Participants are asked to revisit the STI Outpatient Clinic at days 7, 21 and 49 after treatment and to have an extra endocervical specimen collected by speculum examination at each timepoint. Another inconvenience for patients is our request to practice safe sex or refrain from sexual contact during the study period and refrain from vaginal douching. The treatment that patients receive in this study will not pose any other or additional risks than standard of care. The treatment itself is not a point of investigation in this study. We classify this study as having a low chance of possible risks and a low degree of harm, leading to a negligible risk to patients.

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

Born to female sex
Age *18 years
Tested Ct NAAT-positive on urogenital swab
Eligible for azithromycin treatment (no allergies)
Willing to receive the routine treatment for Chlamydia trachomatis at the STI Outpatient Clinic
Accepting conditions of the study and signed informed consent

Exclusion criteria

Tested NAAT-positive on urine sample only
Not being able to give informed consent, based on Dutch or English patient information
Ct infection in the past 3 months
Antibiotic treatment for which Chlamydia trachomatis is sensitive (rifampicin, tetracyclines, macrolides, sulfonamides, quinolones, clindamycin, penicillins, cephalosporins) between day -28 and day 0.
Unlikely to comply with the study requirements

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2015
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	31-03-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	11-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL51851.018.15