Incubation time and test of cure of Chlamydia trachomatis

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Assess duration of Ct positivity in the 8 weeks after treatment as well as the Ct bacterial load and RNA in time-sequential samples

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

Summary

ID

NL-OMON36689

Source
ToetsingOnline

Brief title
Incure

Condition

- Chlamydial infectious disorders

Synonym
Chlamydia, sexually transmitted infections (STI)

Research involving
Human

Sponsors and support

Primary sponsor: GGD Zuid Limburg
Source(s) of monetary or material Support: RIVM;Cib

Intervention

Keyword: Chlamydia trachomatis, DNA, RNA, test of cure

Outcome measures

Primary outcome

- Primary

1. The number of days that Ct is still detected after successful treatment.

Ct-detection by NAAT in time-sequences of self collected material taken after

treatment.

2. The trend in Ct-bacterial load after treatment. Quantifying Ct bacterial

load in time-sequences of self collected material taken after treatment

3. Duration of detection of Ct-RNA (as a marker for viable Ct)

Secondary outcome

- Other

1. Typing the serovar and bacterial DNA (to assess possible reinfection)

2. Duration of detection (DNA and RNA) of Ct in relation to bacterial load

3. Duration of detection of Ct and bacterial load in relation to complaints

4. Duration of detection in relation to presence of Ct-RNA

5. Duration of detection of Ct in relation to serotypes

Study description

Background summary

Chlamydia trachomatis (CT) causes a sexually transmitted disease with major public health consequences due to its frequent asymptomatic nature. Interrupting the route of transmission by timely identifying and treating patients with CT, is an essential intervention in the prevention of this STD. In the Netherlands, the yearly number of CT infections is estimated at 60.000. Currently, Ct detection is regularly performed for diagnosis by using commercially available nucleic acid amplification test (NAAT: PCR or SDA). NAAT is highly sensitive and specific (>99%). Ct is diagnosed among others on

self-taken vaginal swab (women) or anal swab (men and women) which is a valid and well accepted method by both male and female clients. For research and diagnostic purposes a very sensitive and specific in-house PCR was developed as well as a method to test for bacterial load (laboratory of Immunogenetics, VuMC, head Servaas Morré). RNA can be detected as well, e.g. by TMA (GGD Amsterdam). Both for DNA and RNA detection of Chlamydia trachomatis sample collection at home followed by mail delivery is possible.
Fortunately good treatment is available for Ct: present treatment protocols are based on one dose oral antibiotic therapy resulting in successful compliance. It is generally assumed that the standard treatment methods are sufficient to eliminate disease and no microbiological follow-up assessment is recommended. Sometimes, in case of persistent complaints, pregnancy, for reassurance of the client, or potential exposure to a positive source, retesting after 3-4 weeks with NAAT is advised to determine if the infection is properly cleared. In most cases the *test of cure* is recommended not earlier than 3 to 4 weeks after treatment because of possible false positive results by the presence of inactive cell components of Ct. However, there is discussion on the optimal moment of retesting to assess effectivity of treatment. Advise on moment of retesting is based on older studies in which the antibiotic treatment was in most cases different from the current treatment and when the one-dose antibiotic treatment was not yet the standard of care. Most studies also did not include RNA assessment, which indicates that viable Ct is present. Moreover, the current sample method used for CT screening and diagnostic testing in STI clinics and national screening programs (vaginal and anal self-swab) is not studied before.

Study objective

Assess duration of Ct positivity in the 8 weeks after treatment as well as the Ct bacterial load and RNA in time-sequential samples

Study design

Prospective cohort study
During 8 weeks after CT treatment at fixed intervals 17 self-swabs will be taken and three times a short questionnaire will be filled in

Study burden and risks

A self-taken vaginal swab or anal swab is a non-invasive procedure in line with the regular sampling at the STD clinic. (High performance and acceptability of self-collected anal swabs for diagnosis of Chlamydia trachomatis and Neisseria gonorrhea in men and women, manuscript in press STD) Self swab is reported by clients to be an easy to perform method and they would take it again if necessary. It will take about half to one minute to take a self swab. In total the participants are asked to take 17 samples. Patients will participate

individually and no specific groups are targeted.
Thus risks associated with participation are absent or minimal.
Results of this study on the period of detection of CT after treatment, bacterial load and RNA will contribute to the development of 'evidence-based'patient management and on the decrease of spread of CT in the population.

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

- CT positive females (vaginal CT and/or anal CT) who are 18 years of age or older
- Men with positive anal CT diagnosis who are 18 years of age or older

Exclusion criteria

- not living in the Netherlands and not possible to post envelopes in the Netherlands
- Not able to speak/read the Dutch language
- pregnant
- antibiotic use in the week prior to t-1 through t-0
- complicated CT
- location *tippelzone*
- CSI participant

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):	01-07-2009
Enrollment:	55
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-04-2011
Application type:	First submission
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	NL28609.029.09