Detection of Chlamydia trachomatis antibodies in vaginal swabs as an intermediate marker for PID and tubal pathology * pilot study

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To asess whether the Chlamydia Antibody Test (CAT), used to determine the presence of antichlamydia IgG antibodies in serum for diagnostics in the fertility clinic, can serve as an intermediate marker for PID/tubal pathology caused by Chlamydia.

Ethical review	Not approved
Status	Will not start
Health condition type	Chlamydial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON36428

Source
ToetsingOnline

Brief title
Pilot study CAT mucosa

Condition

- Chlamydial infectious disorders
- Sexual function and fertility disorders

Synonym
Chlamydia, PID, tubal infertility

Research involving
Human

Sponsors and support

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

Intervention

Keyword: chlamydia trachomatis, IgG antibody test, vaginal mucosa

Outcome measures

Primary outcome

To compare the presence and quantity/titres of IgG antibodies findings with the health status of the patients regarding current (vaginal) Chlamydia infections, history of prior Chlamydia infections, in lower genital tract (vagina, cervix) or higher parts (pelvic, ovaria: PID) and fertility-related problems (tubal pathology).

Secondary outcome

Depending on the outcomes of this pilot, we aim to set-up a larger study to investigate the prevalence of these antibodies in vaginal samples and the risk for PID prospectively in a dual cohort of women, screened and unscreened.

Study description

Background summary

Chlamydia trachomatis is a common sexually transmitted infection (STI) among young people in the Netherlands. Chlamydia can cause infections higher in the genital tract in women, so-called Pelvic Inflammatory Disease (PID) which can lead to tubal pathology and have serious complications leading to infertility. Chlamydia infection and PID remain asymptomatic in the majority of cases, which makes treatment and prevention difficult. Recently a large Screening Implementation has started among young people in the Netherlands, in order to detect and treat more (asymptomatic) chlamydia infections. Predicting the effect of such a program on later sequelae from infection (PID, ectopic

pregnancy and infertility) is complicated.
Availablity of an itermediate, more proximal and easy to measure marker for tuba-pathology would facilitate the evaluation of screening programmes but also to the course of Chlamydia-infection in a broader sense. If we can predict who has an enhanced risk for complications, targeted interventions can be developed, such as (frequent) screening or more intensive follow-up of partners.

Study objective

To asess whether the Chlamydia Antibody Test (CAT), used to determine the presence of antichlamydia IgG antibodies in serum for diagnostics in the fertility clinic, can serve as an intermediate marker for PID/tubal pathology caused by Chlamydia.

Study design

For this pilot study, we plan to recruit women at two time-points in the path from Ct-exposure and (infiltrating) infection towards PID and tubal pathology: at the time of infection (women consulting STI clinics) and at the time of confirmed longterm complications causing reduced fertility (women consulting fertility clinics).
1. STI clinic Den Haag. Additional material will be collected during routine sampling for STI-consultation, i.e. a vaginal swab and a blood sample from 25 recently infected women (Ct-positive NAAT-test) and matched to 50 women who did not have a Ct-infection at the time of sampling (Ct-negative NAAT-test). Both Ct-positive and *negative women will be asked to answer a few questions on their medical history regarding STIs and PID. The samples will be sent to the laboratory of the Dept Pathology at the VUMC for analyses
2. At the fertility clinics of Groningen and Maastricht Academic centres, we will ask (retrospectively) women who have had a serological CAT in the previous year, to participate in our study (25 CAT-positive and 50 negative). They are requested to collect a vaginal self-sample at home and fill in a short questionnaire and return this to the clinic by mail. Samples will also be sent to the Dept Pathology, VUMC.

At the laboratory, the CAT will be performed on the vaginal samples from the STI clinic and the fertility clinics and on serum from the STI clinic (serum CATs from the fertility clinic are available from patient files). The bacterial load of Chlamydia positive swabs (women with a current Ct-infection from the STI clincic) will be assessed, and we will also quantify the Ct-antibodies in vaginal mucosa and blood of CAT-positive women.

Study burden and risks

The burden for participants to the study is limited to filling in a short

questionnare (10 minutes), furthermore we make use of already available test results (serum CAT in fertiltiy clinic), or we sample additional material within a routine sampling procedure (vaginal swab and bloodsample in STI clinic); only the vaginal self-swab for women who visited the fertility clinic earlier, is additional. There are no further procedures; there are no other risks to be expected.

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 STI-clinics: women who tested positive or negative in a PCR test for (current) genital Chlamydia trachomatis infection and are willing to participate in the study.
In fertility clinic: women who tested positive or negative with serum Chlamydia antibody test (CAT).

Exclusion criteria

In STI clinics: women with coinfection HIV, girls under 18 years old.
In infertility clinic: women with HIV.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Not approved

Date:	18-03-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL33128.042.10