Chlamydia trachomatis antibody test in vaginal swabs as an intermediate marker for PID and tubal pathology - pilot study in fertility clinics

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

Summary

ID

NL-OMON35881

Source
ToetsingOnline

Brief title
CAT study

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: biomarker, Chlamydia trachomatis, IgG antibodies, vaginal swab

Outcome measures

Primary outcome

The main outcome parameters are presence and quantity (titer) of IgG Chlamydia

antibodies in vaginal swabs and in serum.

Secondary outcome

not applicable

Study description

Background summary

Chlamydia trachomatis (Ct) is a common sexually transmitted infection among adolescents. In women lower genital tract infections (cervicitis) may ascend to the upper genital tract and cause Pelvic Inflammatory Disease (PID), which may lead to tubal pathology and subsequent infertility. Chlamydia cervicitis and PID often remain asymptomatic, which makes treatment and prevention of late sequelae difficult. Furthermore, it may take a decade or more before late complications (infertility) become evident, and for diagnosing tubal pathology an invasive and costly procedure (i.e. laparoscopy) is required. An intermediate, non-invasive biomarker that could predict late complications of Ct infection would enable identification of women at high risk for complications and facilitate effect evaluation of interventions aimed at reduction of the prevalence of complications of Chlamydia.
It has been known for many decades that in infertile women tubal pathology is associated with the presence of Chlamydia IgG antibodies in serum. In fertility clinics, the Chlamydia IgG Antibody test (CAT) in serum (serum-CAT) is used as a screening test for tubal pathology, and for selecting high risk patients for laparoscopy. So far it has not been studied whether CAT can be tested by alternative non-invasive means, i.e. in self collected vaginal swabs of mucosa

instead of in serum.

Study objective

We will investigate whether Chlamydia IgG antibody presence and titers in vaginal swabs (mucosa-CAT) are comparable to antibodies found in serum (serum-CAT), and as such could serve as a marker for a past Chlamydia infection with an enhanced risk of complications.

Study design

Comparative diagnostic study, comparing already available results of serum-CAT with results of mucosa-CAT in women attending the fertility clinics of the University Medical Centers in Groningen and Maastricht. Recruitment will continue until a number of 25 serum-CAT positive and 50 serum-CAT negative women is reached. The partcicipants will be asked to respond to a short questionnaire and collect a vaginal self-swab.

Study burden and risks

Eligible patients will receive a written request to participate. After consent is given, they receive a short questionnaire on past Chlamydia infections and PID and a test-kit with a vaginal swab for self-collection which can be returned by mail. There are no risks for the participating women, and for them there are no direct, individual benefits.

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

We will actively recruit women who are registered at the fertility clinic in the UMCG or MUMC and had a serum-CAT taken and preferably also undergone laparoscopy examination within the previous year as part of their fertility work-up.

Exclusion criteria

Informed consent should be obtained from the patient. Women who do not attend the fertility clinic any more or who have become pregnant will not be approached.

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):	06-01-2012

Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	21-09-2011
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	NL36895.042.11