The Netherlands Chlamydia Cohort Study: assessing the risk of late complications after Chlamydia trachomatis infection in women

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

Summary

ID

NL-OMON55823

Source
ToetsingOnline

Brief title
The NEtherlands Chlamydia Cohort STudy (NECCST)

Condition

- Chlamydial infectious disorders
- Pregnancy, labour, delivery and postpartum conditions
- Ovarian and fallopian tube disorders

Synonym
Chlamydia, Chlamydia trachomatis

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Aanvraag ZonMw subsidie (toegekend najaar 2020),RIVM

Intervention

Keyword: Chlamydia trachomatis, Pelvic Inflammatory Disease, Pregnancy, Subfertility

Outcome measures

Primary outcome

The main outcomes of the study are PID, ectopic pregnancy, tubal infertility

and time to pregnancy. The primary study parameter is the presence of a

previous Ct infection.

Secondary outcome

The secondary study parameters include candidate host genetic biomarkers (SNPs)

and behavioural, demographic, and pathogen factors possibly associated with the

development of Ct related complications.

Study description

Background summary

Chlamydia trachomatis (Ct) is a common sexually transmitted infection (STI) among young people. Although the course of infection is often asymptomatic, Ct may lead to severe complications in women, such as pelvic inflammatory disease (PID), prolonged time to pregnancy, ectopic pregnancy, and tubal infertility. Since various transmission control strategies have not been successful in reducing Ct prevalence, it may be more effective to focus on prevention of complications after a Ct infection. Until now, the risk of complications after Ct has not been assessed directly in a prospective cohort study, but only in modelling studies. The estimates of complication risk after Ct vary widely between these studies. Furthermore, factors that contribute to the development of complications after Ct remain to be elucidated.

Study objective

The aim of the NEtherlands Chlamydia Cohort STudy (NECCST) is to assess the risk of developing complications and the time to pregnancy in women with and without a known previous Ct infection. Furthermore, this study aims at determining host genetic biomarkers and behavioural, demographic, and pathogen factors that are associated with the development of these complications.

Study design

NECCST is a cohort study and a continuation of the Chlamydia Screening Implementation (CSI), which was executed between 2008 and 2011 in Rotterdam, Amsterdam, and South-Limburg, among people between 16 and 29 years of age. In the CSI, persons were invited to be tested for Ct. Of all participants who gave informed consent, biological samples have been stored in a Biobank. In NECCST we will recruit all CSI women who consented to be approached for follow-up (2,371 CSI Ct positive women and 12,314 CSI Ct negative women), and prospectively follow them until 2022. Samples stored in the CSI Biobank will be used to measure the presence of candidate host genetic biomarkers (Single Nucleotide Polymorphisms (SNPs)). In case the sample is absent or of insufficient quality, a new sample (buccal swab) will be obtained in 2015. During NECCST, four data collection moments are foreseen: in 2015, 2017, 2019, and 2021. Participants will be asked to fill in an online questionnaire at every data collection moment. In case women report infertility/subfertility in the questionnaire, medical records will be checked to identify the cause of their infertility/subfertility. A separate informed consent will be obtained for this medical record check, after the women have indicated infertility/subfertility in the questionnaire. At the first and last data collection moment, participants will also be asked to provide a blood sample at home (blood drops in a collection tube), in order to measure Immunoglobulin G (IgG) antibodies for Ct, as a marker of a previous Ct infection.

Study burden and risks

Participating women will not be subject to any health risk. However, participants may experience some discomfort by the personal nature of the questionnaire (e.g. questions on sexual behaviour; however, similar to the ones they answered during the Chlamydia Screening Implementation), and by the (self)collection of blood samples at home.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Being a women;
- Participated in at least one round of the Chlamydia Screening Implementation between 2008 and 2011;
- Given informed consent in the Chlamydia Screening Implementation to be contacted again for future STI-related research.

Exclusion criteria

- Not living in the Netherlands anymore;
- No traceable address information.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2015
Enrollment:	14685
Type:	Actual

Ethics review

Approved WMO Date:	13-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	03-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-09-2021
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	NL51553.094.14