# The Netherlands Chlamydia Cohort Study

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON23749

**Source**
NTR

**Brief title**
NECCST

**Health condition**

Genital Chlamydia trachomatis infection
Pelvic Inflammatory Disease (PID)
Ectopic pregnancy
(Tubal) infertility
Prolonged time to pregnancy

Genitale Chlamydia trachomatis infectie
PID
Ectopische zwangerschap
Tubaire infertiliteit
Verlengde duur tot zwangerschap

### Sponsors and support

**Primary sponsor:** National Institute for Public Health and the Environment (RIVM)
VUmc
**Source(s) of monetary or material Support:** ZonMw
RIVM

## Intervention

## Outcome measures

### Primary outcome

The main outcomes of the study are Pelvic Inflammatory Disease (PID), ectopic pregnancy, tubal infertility and time to pregnancy. The primary study parameter is the presence of a previous Chlamydia trachomatis 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 Chlamydia trachomatis related complications.

# Study description

### Background summary

Rationale: 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 modelling studies. Furthermore, factors that contribute to the development of complications after Ct remain to be elucidated.

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 buccal sample 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. At the first and last data collection moment, participants will also be asked to provide a blood sample at home in order to measure Immunoglobulin G (IgG) antibodies for Ct, as a marker of a previous Ct infection. In case women report subfertility/infertility in the questionnaire, the underlying cause will be determined in their medical register.

Study population: All women participating in the CSI who gave informed consent to be contacted again for future STI-related research.

Main study parameters/endpoints: The main endpoints are PID, ectopic pregnancy, tubal infertility and time to pregnancy. The main study parameter is the presence of a previous Ct infection. The secondary study parameters include candidate host genetic biomarkers and behavioural, demographic, and pathogen factors possibly associated with the development of Ct related complications.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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 CSI), and by the (self)collection of a blood sample at home.

**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 Chlamydia trachomatis (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. The ultimate goal will be to develop a prognostic tool to estimate the risk of complications after a Ct infection at an early time point, e.g. when a woman is diagnosed with Ct in an STI clinic. This may benefit targeted secondary preventive measures in women at high risk of complications. Furthermore, it can aid triage of women requiring laparoscopy in fertility clinics.

**Study design**

Four data collection moments are foreseen: in 2015/2016, 2017/2018, 2019/2020, and 2021/2022. Participants will be asked to fill in an online questionnaire at every data collection moment. At the first and last data collection moment, participants will also be asked to provide a blood sample at home in order to measure Immunoglobulin G (IgG) antibodies for Ct, as a marker of a previous Ct infection. In case women report subfertility/infertility in the questionnaire, the underlying cause will be determined in their medical register.

**Intervention**

NA

# Contacts

**Public**
Postbus 1

Bernice Hoenderboom
Bilthoven 3720 BA
The Netherlands
+31302744766
**Scientific**
Postbus 1

Bernice Hoenderboom
Bilthoven 3720 BA
The Netherlands
+31302744766

# Eligibility criteria

## 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

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |

**Control:** N/A , unknown

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 26-10-2015 |
| Enrollment: | 14685 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 18-12-2015 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL5453 |
| NTR-old | NTR5597 |
| Other | METC Noord-Holland : 51553 |

# Study results