

Mathematical models incorporating Psychological determinants: control of Chlamydia Transmission

Published: 08-08-2016

Last updated: 15-05-2024

We aim to study the link between behavioural and psychological determinants and chlamydia (re-)infection, and to develop mathematical models for curable STI incorporating these determinants to be able to better estimate the impact of interventions.

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

Summary

ID

NL-OMON46321

Source

ToetsingOnline

Brief title

iMPaCT

Condition

- Chlamydial infectious disorders
- Ovarian and fallopian tube disorders

Synonym

Chlamydia, Chlamydia trachomatis infection

Research involving

Human

Sponsors and support

Primary sponsor: RIVM

Source(s) of monetary or material Support: RIVM (SPR MDM)

Intervention

Keyword: Chlamydia trachomatis, Infectious Disease Modelling, Psychological Determinants, Sexual Behaviour

Outcome measures

Primary outcome

The main parameters of the study are chlamydia (re-)infection and demographic, behavioural and psychological determinants.

Secondary outcome

N/A

Study description

Background summary

Chlamydia is the most commonly reported STI in the Netherlands and the number of reported cases has been increasing in the past few years. Control of this infection is of public health importance, because chlamydia infections are associated with increased risk of serious reproductive consequences, such as pelvic inflammatory disease (PID), ectopic pregnancy and infertility. However, control of chlamydia has proven to be challenging; reasons for this might be high re-infection rates after treatment. Therefore, behaviour change after a diagnosis might be vital to reduce re-infection rates. In addition, because most people are unaware of their infection, preventive health actions (such as using condoms) depend on psychological determinants, making the incorporation of such determinants in models especially important in this field. Ultimately, the data collected in the clinical study will be used to parameterise a mathematical model, which will provide valuable information for public health policy makers to guide which intervention measures should be prioritised and conducted in the future.

Study objective

We aim to study the link between behavioural and psychological determinants and chlamydia (re-)infection, and to develop mathematical models for curable STI incorporating these determinants to be able to better estimate the impact of interventions.

Study design

The aim of the clinical study (longitudinal cohort study) is to collect data on sexual behaviour and psychological determinants from people visiting STI clinics. Participants are enrolled for a year, and questionnaires are administered at four time points: at baseline, 3 weeks, 6 months and at one year follow-up. To be able to link behavioural and psychological determinants to (re-)infections, participants will be tested for chlamydia at enrolment and at 6 months follow-up.

Study burden and risks

There are no health risks associated with participation. However, participants may experience some discomfort by the personal nature of the questionnaire and by the collection of vaginal swabs and urine samples (at the STI clinic and at home).

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

- Being a heterosexual man or woman
- Between 18 and 24 years old;
- Not notified by partner

Exclusion criteria

- Not living in the Netherlands
- Inability to read or speak Dutch
- Men who have sex with men (MSM), women who have sex with women (WSW) and men/women who have sex with both men and women

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): 08-11-2016

Enrollment: 2000

Type: Actual

Ethics review

Approved WMO

Date:	08-08-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	10-11-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28873

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL57481.094.16
OMON	NL-OMON28873