Chlamydia Screening Implementation Project

Published: 19-03-2008
Last updated: 11-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Chlamydial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON32112

Source
ToetsingOnline

Brief title
CSI-Project

Condition

- Chlamydial infectious disorders

Synonym
Chlamydia trachomatis, std, venereal disease

Research involving
Human

Sponsors and support

Primary sponsor: Zorgonderzoek Nederland (ZON)
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: chlamydia, home-based, internet-based, selective systematic screening

Outcome measures

Primary outcome

· Response rate of 30% (individuals who actually send in their samples to the laboratory)

· Ct-positivity rate between 3-5%

Secondary outcome

Impact of Chlamydia screening on ct-prevalence (which can be achieved by chlamydia trend analysis) and the impact on PID-rates.

The results of this implementation will be leading for the decision about the national roll-out of screening in the Netherlands.

Study description

Background summary

Early detection and treatment (screening) of infections with Chlaymydia trachomatis (CT) is a strategy to reduce complications in infected individuals and to limit the spread of the infection in the population. In a recent publication, the National Health Council advises to start a pilot implementation. The Minister of Health has now issued a directive to perform such a pilot implementation.

Study objective

The aim of this pilot implementation is first to make a serious start in Chlamydia screening and secondly to determine feasibility, affectivity and cost-effectivity. The results of this pilot implementation will be leading for the decision about the national roll-out of screening in the Netherlands.

Study design

Intervention study by means of a selective systematic home-based screening. Three hundred fifteen thousand persons will be invited to participate two times in a 3 year period. They will be invited according to the so called stepped wedge cluster-randomized designwithin randomized clusters. Stepped wedge design is a *Sequential roll-out of an intervention to individuals (or clusters) over a number of time periods. By the end of the study, all participants have received the intervention, although the order in which they receive the intervention is determined at random*.

Intervention

Implementation (regional) of selective systematic home-based screening for chlamydia trachomatis. In Amsterdam and Rotterdam (high population density) all members of the target population will be invited to participate. In the eastern part of the lower population density area South Limburg, only part of the target population will be invited based on a specific risk analysis

Study burden and risks

Screening might have potential side effects. These effects relate to issues like somatic fixation (feeling dirty; *am I now infertile?*), negative consequences in the partner relation and a potential negative effect on safer sex (*I have myself tested and don*t need to do it safe*). However, in our PILOT CT study we did not find evidence that intention for safer sex decreased, and among persons tested positive it even increased. Thus, screening can also have positive side effects and be instrumental to discuss safer sex and give rise to tailored prevention counselling in primary care. Acceptance of the screening approach will be studied during the evaluation

The target population are sexually active individuals in the 16 to 29 age bracket. Minors (16 and 17) are also included because both nationally (Pilot Ct) as internationally it has been clear that individuals of 25 years and younger are a very important group to include in screening projects due to their relatively high background prevalence.
No medical risks for the participants are involved in this implementation project.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

16-29 age bracket
sexual active
registred in standard municipal registers of Amsterdam/Rotterdam/South Limburg

Exclusion criteria

Younger than 16 years
Older than 29 years
not sexual active

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	315000
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL19809.029.07