

What is the optimal time to retest patients with a urogenital chlamydia infection?

Submission date 01/05/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 09/05/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/11/2017	Condition category Infections and Infestations	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Chlamydia is a common sexually transmitted infection. The current guidelines recommend testing again after a chlamydia infection, but the best timing is not known. The aim of this study is to find the best time to retest after chlamydia treatment.

Who can participate?

Heterosexual patients of the Amsterdam STI clinic with a chlamydia infection, aged 12 or older

What does the study involve?

After being diagnosed and treated, participants are randomly allocated to be offered a retest either 8, 16 or 26 weeks later. Participants can choose to do this at home and send a self-collected sample by mail, or at the clinic. The number and percentage of participants retested and chlamydia infection rates are assessed up to 35 weeks later.

What are the possible benefits and risks of participating?

The benefit for the participant is that chlamydia re-infections are diagnosed and treated. There are no risks involved in participation.

Where is the study run from?

Public Health Service (GGD) Amsterdam (Netherlands)

When is the study starting and how long is it expected to run for?

May 2012 to April 2017

Who is funding the study?

Public Health Service (GGD) Amsterdam (Netherlands)

Who is the main contact?

Prof. Henry de Vries

Contact information

Type(s)

Scientific

Contact name

Prof Henry de Vries

ORCID ID

<https://orcid.org/0000-0001-9784-547X>

Contact details

Public Health Service
Department of Infectious Diseases
Nieuwe Achtergracht 100
Amsterdam
Netherlands
1018WT

Additional identifiers**Protocol serial number**

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Study information**Scientific Title**

What is the optimal time to retest patients with a urogenital chlamydia infection? A randomized controlled trial

Study objectives

The trialists postulated that in heterosexual visitors of the STI clinic with a urogenital chlamydia infection, the proportion being retested would be lower with a later timing of retest, and that the proportion positive would be higher with a later timing of retest. If so, the trialists envisioned an optimum timing to offer a retest, which would provide the highest yield of diagnosed reinfections.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was reviewed by the ethics committee of the Academic Medical Center, University of Amsterdam, Netherlands. The board exempted the study from a full review and written patient consent as it was a modification of current practice and did not apply to the Dutch law 'Medical Research Involving Human Subjects Act (WMO)'.

Primary study design

Interventional

Study design

Single-centre randomized controlled trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Urogenital Chlamydia trachomatis infection

Interventions

A single-centre randomized controlled trial among urogenital chlamydia nucleic acid amplification test positive heterosexual Amsterdam STI clinic clients. After treatment, patients were randomly assigned for retesting 8, 16 or 26 weeks later. Patients could choose to do this at home (and send a self-collected sample by mail), or at the clinic. Retest uptake and chlamydia positivity at follow-up were calculated.

Intervention Type

Other

Primary outcome(s)

1. The number and percentage of participants retested up to 35 weeks after inclusion
2. The proportion of participants who were CT positive, measured by nucleic acid amplification test, up to 35 weeks after inclusion

Key secondary outcome(s)

1. The number, percentage and chlamydia positivity proportion of participants who:
 - 1.1. Returned more than 1 week before the assigned date
 - 1.2. Returned at assigned date (this was defined as a visit in the period >1 week before, until 6 weeks after the assigned date)
 - 1.3. Returned >6 weeks after the assigned date but no later than 35 weeks (8 months) after inclusion
 - 1.4. Those who did not return within 35 weeks of inclusion

Completion date

01/04/2017

Eligibility**Key inclusion criteria**

1. Heterosexual patients of the Amsterdam STI clinic testing positive for urogenital chlamydia
2. Aged 12 years or older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/05/2012

Date of final enrolment

01/03/2013

Locations**Countries of recruitment**

Netherlands

Study participating centre

Public Health Service (GGD) Amsterdam

STI outpatient clinic

Department of Infectious Diseases

Weesperplein 1

Amsterdam

Netherlands

1018 WT

Sponsor information**Organisation**

Public Health Service

ROR

<https://ror.org/042jn4x95>

Funder(s)**Funder type**

Government

Funder Name

Public Health Service (GGD) Amsterdam

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Henry de Vries.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018		Yes	No