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

Submission date
01/05/2017

Recruitment status
No longer recruiting

Registration date
09/05/2017

Overall study status
Completed

Last Edited
14/11/2017

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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1018WT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
-

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)’.

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures
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

Overall study start date
01/05/2012

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

Age group
Mixed

Sex
Both

Target number of participants
2500

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

Sponsor details
Department of Infectious Diseases
Nieuwe Achtergracht 100
Amsterdam
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Sponsor type
Government

Website
ggd.amsterdam.nl

ROR
https://ror.org/042jn4x95

Funder(s)

Funder type
Government

Funder Name
Public Health Service (GGD) Amsterdam

Results and Publications

Publication and dissemination plan
The trialists have presented the preliminary results during two scientific meetings, in 2013 during the international society for STD Research (ISSTDR) meeting in Vienna, Austria, and in 2014 during the International Society for Human Chlamydia Infection (ISHCI) meeting in Monterrey, CA, USA. Currently they are submitting the definite results to a scientific peer reviewed journal.

Intention to publish date
15/05/2017

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