# Pharyngeal chlamydia; temporary colonisation or persistent infection? A prospective observational study

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What is the proportion of STI outpatient clinic visitors with a persistent colonisation of chlamydia in the pharynx up until 3 weeks after the first diagnosis based on a NAAT positive chlamydia pharyngeal swab.

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Bacterial infectious disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON34207

**Source**
ToetsingOnline

**Brief title**
Pharyngeal chlamydia

### Condition

- Bacterial infectious disorders
- Female reproductive tract infections and inflammations
- Skin and subcutaneous tissue disorders

**Synonym**
chlamydia infection of the throat

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** GGD Amsterdam

**Source(s) of monetary or material Support:** Research en development fonds van de GGD Amsterdam

## Intervention

**Keyword:** Azithromycine, Chlamydia trachomatis, Infectious disease, Sexually transmitted infection (STI)

## Outcome measures

### Primary outcome

Subsequent positive chlamydia throat swab

### Secondary outcome

Riskfactors associated with (the presistence of) chlamydia in the throat.

Chlamydia bacterial load in subsequent throat swabs

# Study description

### Background summary

Modern nucleic acid amplification tests (NAAT) are far more sensitive to detect infectious pathogens compared to older diagnostic cultivation methods. A few copies of DNA can cause a positive test result, yet its relevance is not known. Many pathogens can only infect specific bodily tissues and give rise to disease (tissue trophism). Outside these tissues modern NAAT can (temporalily) detect the precence of these organisms but the host immune system is capable to eliminate the pathogens swift and efficient, thus preventing disease or further transmission.
It is known that pharyngeal gonorrhea infections remain asymptomatic in 90% of cases and are eliminated by the host within 3 weeks. Swift elimination of gonorrhea from the pharynx is explained by low tissue tropism of the organism for this location. Yet it is shown that screening for pharyngeal gonorrhea infections is of relevance since they contribute to the transmission of gonorrhea to partners via receptive oral sexual contact. (Linhart 2008) In this project we will study the natural course of patients with a positive pharyngeal swab for chlamydia.

### Study objective

What is the proportion of STI outpatient clinic visitors with a persistent

colonisation of chlamydia in the pharynx up until 3 weeks after the first diagnosis based on a NAAT positive chlamydia pharyngeal swab.

**Study design**

Chlamydia persistence in the pharynx up until 3 weeks
Participants:
86 STD-clinic visitors consisting of 43 men who have sex with men (MSM) and 43 women who have sex with men (WSM)

Inclusion criteria:
oReceptive oral sex in the last 6 months (t-7)
- Pharyngeal swab (obtained on t-7 for the exclusion of a gonorrhea infection) is chlamydia positive (based on the TMA Aptima Combo 2 assay NAAT, streeklab GGD Amsterdam).

Exclusion criteria:
oAge under 18 years
-Other bacterial STD (gonorrhea, syphilis, lymphogranuloma venereum, chlamydia) at t-7.
oafter the pharyngeal swab has been obtained the patient has been treated with Ct sensitive antibiotics (rifampicin, tetracyclines, macrolides, sulfonamides, quinolones, clindamycin, penicillins, cephalosporins).

Inclusion visit (t0);
-explaination of the study, sign informed consent and inclusion
-quationnaire e.g oral sexual contact.
osecond pharyngeal swab obtained for Ct determination (TMA Aptima Combo 2 assay)
ocontact tracing and treatment according to routine procedure.
- receptive oral sexual contact until the next visit is not allowed.
ò new appointment after 7 days

Second visit (t +7);
-questionnaire about oral sexual contact in the past week.
obtain a third pharyngeal swab for Ct determination (TMA Aptima Combo 2 assay)
-receptive oral sexual contact until the next visit is not allowed.
ò new appointment after 7 days

Third visit (to 14);
-questionnaire about oral sexual contact in the past week.
obtain a third pharyngeal swab for Ct determination (TMA Aptima Combo 2 assay)
-treat with azithromycin 1000 mg once

-Bacterial load determination in pharyngeal swabs at t = -7, t = 0, t = 7 and t 14 (lab pathology VUMC)

end of the study

**Study burden and risks**

Apart from the routine diagnostic screening for STD's, 3 additional throat swabs and a questionnaire on oral sexual contact are obtained. The associated risk is nil

# Contacts

**Public**
GGD Amsterdam

Weesperplein 1
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NL
**Scientific**
GGD Amsterdam

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Receptive oral sexual contact in the past 6 months
A pharyngeal swab positive for Chlamydia (based on the TMA Aptima 2 combo NAAT assay)

### Exclusion criteria

Other bacterial STI
Use of antibiotics after collection of the pharyngeal swab

## Study design

### Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-10-2010 |
| Enrollment: | 86 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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| 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 | NL33651.018.10 |