Detection of Treponema pallidum DNA at various body locations

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(1) To determine the presence of T. pallidum DNA as proxy for the infectiousness of peripheral blood, urethral, anal and pharyngeal mucosa in infectious syphilis. (2) To evaluate T. pallidum polymerase chain reaction test (Tp-PCR) to diagnose…

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

Summary

ID

NL-OMON46109

Source
ToetsingOnline

Brief title
The presence of syphilis bacteria at various body locations

Condition

- Bacterial infectious disorders

Synonym
Syphilis, Treponema pallidum

Research involving
Human

Sponsors and support

Primary sponsor: GGD Amsterdam
Source(s) of monetary or material Support: GGD Amsterdam

Intervention

Keyword: Diagnosis, Polymerase Chain Reaction (PCR), Syphilis, Treponema pallidum

Outcome measures

Primary outcome

The presence of Tp-DNA load in pharyngeal, rectal, urine and peripheral blood

samples; RPR syphilis titer, and infection stage

Secondary outcome

Sensitivity, specificity, predictive values (positive and negative) and area

under the curve (AUC) of the Tp-PCR assay in pharyngeal, rectal, urine and

blood samples.

Study description

Background summary

Syphilis rates worldwide are on the rise, in the Western world especially among men who have sex with men (MSM). In an era with pre-exposure prophylaxis against HIV infection and subsequent risk compensation it is feared that the number of infections may become even higher. Syphilis is routinely diagnosed on clinical findings and serologic tests. However in the early stages of the infection, serology may be false negative, and syphilis may be asymptomatic. This poses challenges in the diagnosis and missed infections may lead to onward transmission and late sequelae. Moreover, the mode of transmission, especially in asymptomatic patients, is not well understood.

Study objective

(1) To determine the presence of T. pallidum DNA as proxy for the infectiousness of peripheral blood, urethral, anal and pharyngeal mucosa in infectious syphilis.
(2) To evaluate T. pallidum polymerase chain reaction test (Tp-PCR) to diagnose infectious syphilis, when applied on urine, peripheral blood and on anal and pharyngeal mucosal samples.
(3) To obtain DNA samples from more patients with syphilis in order to improve

studies on molecular epidemiology.

Study design

A cohort study

Study burden and risks

This study is developed to get a better understanding of transmission and diagnostics in early syphilis. There are no additional risks for participants. In participants with an negative syphilis serology or negative Tp-PCR ulceration result who have an early incubating diagnosis, this study may be of benefit, since it would have been missed with the routine screening algorithm. If Tp-PCR on mucosal swabs, urine or peripheral blood has added value, implementation will be considered for routine practice.

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

-18 years or older
- Being male and have had sex with males in the past 6 months

Exclusion criteria

Exclusion criteria
- Use of antibiotics within 4 weeks prior to inclusion
- Use of antibiotics within 12 weeks after inclusion in participants with positive Tp-PCR results

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2018
Enrollment:	285
Type:	Actual

Ethics review

Approved WMO

Date:	26-09-2018
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	NL66419.018.18