Follow-up after treatment of Neisseria gonorrhoeae infections, when and how is a test-of-cure to be included in routine? A prospective observational cohort study

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

Summary

ID

NL-OMON38963

Source
ToetsingOnline

Brief title
Test-of-cure for Neisseria gonorrhoeae

Condition

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

Synonym
gonorrhoea, Neisseria gonorrhoeae

Research involving
Human

Sponsors and support

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

Intervention

Keyword: APTIMA Combo 2, Cobas 4800, Neisseria gonorrhoeae, Test-of-cure

Outcome measures

Primary outcome

The primary endpoints are clearance of Ng infection and time to clearance in

days determined by NAAT.

Secondary outcome

Secondary endpoints are clearance per anatomical location and intermittent

presence of bacterial DNA and/or RNA.

Study description

Background summary

Gonorrhoea, caused by Neisseria gonorrhoeae (Ng), is the most prevalent bacterial sexually transmitted infection (STI) globally. If left untreated infection with Ng can result in complications including pelvic inflammatory disease, ectopic pregnancy, infertility, epididymitis or prostatitis. To diagnose Ng national and international guidelines increasingly recommend the use of a nucleic acid amplification test (NAAT). This method has very high sensitivity and specificity for Ng, but lacks the possibility to determine antimicrobial resistance (AMR), which is done by direct cultivation. Surveillance of AMR is important as Ng has shown a remarkable ability for rapid development of resistance to any type of antimicrobials that have been used to treat it so far. Recently multidrug-resistance and treatment failures even with the last available type of antibiotics (extended-spectrum cephalosporins, ESC) have been reported, making Ng possibly untreatable in the near future.
In the light of increasing AMR and necessary surveillance a test-of-cure (TOC) is strongly advocated by e.g. WHO. Yet information on the appropriate timing of TOC with a NAAT is highly limited and inconsistent.

Study objective

The primary objective is: The minimum time in days after treatment for Ng to perform a TOC using NAAT and DNA PCR. Secondary objectives are: Time to clearance per infected location. Host and pathogen related factors associated with time to clearance. Occurrence of intermittent bacterial DNA or RNA positivity after treatment.

Study design

In this prospective observational cohort study 60 patients visiting the STI outpatient clinic will be included. Inclusion criteria are: 18 years of age or older, Ng infection confirmed at the STI Outpatient Clinic: anorectal or urethral in males, endocervical, vaginal or anorectal in females, accepting routine treatment. Included patients will self-sample daily for 28 consecutive days following treatment. The collected samples will be analysed by NAAT (APTIMA Combo 2® assay) and DNA PCR (cobas® 4800) to evaluate time to clearance and provide answers regarding the time and place of TOC in routine practice.

Study burden and risks

This study will require patients to take daily samples, fill out a short diary, use condoms consistently or abstain from sexual contact during the study period, abstain from vaginal/rectal douching during the study period and return to the STI clinic for an end of study visit.
No risks or harms are involved in this study. Benefit of the individual patient is the monitoring of their therapy effect and clearance of the Ng infection.

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
Infection with Neisseria gonorrhoeae of urethra, vagina/cervix and/or anal canal
Infection with Neisseria gonorrhoeae diagnosed by Gram-stained smear, APTIMA Combo 2 (NAAT) and/or direct cultivation
Willing to receive the routine treatment for Ng

Exclusion criteria

Use of antibiotics one week prior to gonorrhoea treatment
Current pregnancy in females
Only urethral infection in females
Ng infections diagnosed by Gram-stained smear, but subsequently not confirmed by NAAT or cultivation.

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):	10-03-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	04-10-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-02-2014
Application type:	Amendment
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	NL45935.018.13