Pharmacokinetics and pharmacodynamics of drugs for Nontuberculous Mycobacterial diseases in Dutch patients

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To describe the steady state pharmacokinetics of rifampicin, desacetylrifampicin, ethambutol, claritromycin, 14alpha-OH clarithromycine and azithromycin in plasma of adult patients with NTM infections in the Netherlands

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mycobacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON32679

Source
ToetsingOnline

Brief title
PK and PD of drugs for Nontuberculous Mycobacterial diseases

Condition

- Mycobacterial infectious disorders

Synonym
non tuberculous mycobacteria

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: mycobateria, nontuberculous, pharmacodynamics, pharmacokinetics

Outcome measures

Primary outcome

Pharmacokinetic parameters of antimycobacterial drugs in NTM treatment

Secondary outcome

1. Determinants of pharmacokinetic parameters

2. Assessment of MIC values and pharmacodynamic parameters for response.

3. Association of pharmacokinetic and pharmacodynamic parameters with treatment outcome and toxicity.

Study description

Background summary

NTM are widely distributed in the environment and can especially be found in soil and water sources. These bacteria a very similar to tuberculosis bacteria. We are not that long aware that these bacteria can cause illness. Especially in patients with a chronic lung disease are sensitive to these bacteria and are susceptible to develop an infection. A lot of ambiguity consists about the best treatment of these infections. Up till now mainly the normal treatment for tuberculosis is used, however, the time period during which these medicines should be used and what dose should be used is mainly unknown.

To investigate whether the dose used at this moment is right a pharmacokinetic curve will be taken at steady-state.

Study objective

To describe the steady state pharmacokinetics of rifampicin, desacetylrifampicin, ethambutol, claritromycin, 14alpha-OH clarithromycine and azithromycin in plasma of adult patients with NTM infections in the Netherlands

Study design

This is a prospective observational study in which pharmacokinetic and pharmacodynamic parameters are evaluated in a cohort of patient with NTM diseases.

Study burden and risks

Extra time investment for three extra outpatient controls and the day of hospitalisation for the PK curve.
Installing a Venflon can cause pain and light bruising during introduction.
Keeping a medication diary will take a few minutes per day.

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

Patients:
•Currently treated for NTM infection or recently diagnosed with NTM infection starting treatment at ULC Dekkerswald, Groesbeek, or Centre for Revalidation Beatrixoord, Haren, the Netherlands.
•Diagnosis and treatment according to ATS criteria for NTM infections. Patients with pulmonary (eventually with extrapulmonary localizations) NTM infections are eligible.
•Treated with at least rifampicin and ethambutol and optionally with claritromycin or azitromycin on a daily basis.
•Age >=18 years.
•Patient has been using drugs for at least two weeks when steady state concentrations of rifampicin and azithromycin is expected.
•Informed consent has been signed.

Exclusion criteria

•The medical state of the patients does not allow inclusion according to the physician in attendance.
•The patients* clinical parameters urge immediate cessation of drugs.
•The patient is pregnant.
•Significant hepatic or renal dysfunction
•Patients with cystic fibrosis, since these show deviating pharmacokinetics for many drugs.
•Patients with HIV infection

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-01-2010

Enrollment:	26
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	14-12-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL29420.091.09