Evaluation of in vitro assays (lymphocyte proliferation assays, cytokine production assays and/or T spot TBtm and/or Quantiferon-TB Gold) during follow-up of individuals with recent Mantoux skin test conversion, or (latent or clinically active) Tuberculosis.

Published: 16-07-2007
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Hypothesis:- The height of the result of the MTB-specific assays is directly related to the number of MTB bacilli present. As a result, effective treatment of persons with LTBI will cause a decrease of the quantitative test result and finally a...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Immunodeficiency syndromes
Study type	Observational non invasive

Summary

ID

NL-OMON31206

Source
ToetsingOnline

Brief title
C09/ad

Condition

- Immunodeficiency syndromes

Synonym
prevention, Tuberculosis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Evaluation, in vitro assays, latent clinically active, Tuberculosis

Outcome measures

Primary outcome

nvt

Secondary outcome

T Spot TB and Quantiferon-TB Gold.

Study description

Background summary

In case of exposure to contagious pulmonary tuberculosis about 25 to 50% of the inner family members become infected about 15% develop clinically active tuberculosis of whom about halve develop contagious pulmonary disease and can spread the disease further.
The reason why some individuals develop disease (<15%) wheras others remain healthy (>85%) and contain the outgrowth of Mycobacteria, is uncertain. Likely, both environmental a well as host genetic fectors play a role in this process, as do the specifics of the bacteria.

Study objective

Hypothesis:

- The height of the result of the MTB-specific assays is directly related to the number of MTB bacilli present. As a result, effective treatment of persons with LTBI will cause a decrease of the quantitative test result and finally a negative result of the assays. On the other hand, a rise of the responses to MTB-specific antigens and low or decreasing responses to latency antigens in

untreated latently infected persons may predict development to active TB disease

Aims of the study:

- The primary aim is to follow-up persons diagnosed with a positive TST result or latent or clinically active tuberculosis, using In Vitro assays and immune responses to various latency antigens in order to relate the time course of test results to 1. the effect of treatment and 2. the prediction of active TB/surrogate marker of protection.
-Should additional relevant questions arise during the evaluation of het large dataset that was obtained during the preceding study, these will be presented to the Ethical Review Board for evaluation.

Study design

Prospective cohort study following up TST positieve individuals and individuals being treated for latent or clinically active Tuberculosis.

Study burden and risks

Five times venapunction in two years time.

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

Age at least 18 Years at time of entry into the study.
Positive TST result during a contact investigation, or being (have been) treated for latent or active tuberculosis.
Written informed consent.

Exclusion criteria

nvt

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-04-2007
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL16554.058.07