QUantiferon in Active and Latent Infection with Tuberculous mYcobacteria

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Primary Objectives: To explore whether QFT-plus is equipped to differentiate between active TB disease and latent TB infectionTo explore a possible correlation between QFT-plus response and time after TB-infection and/or diagnosis tuberculosis /...

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

Summary

ID

NL-OMON42494

Source
ToetsingOnline

Brief title
QUALITY-study

Condition

- Mycobacterial infectious disorders

Synonym
TB, Tuberculosis

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Firma Qiagen (Verstrekking Quantiferon PLUS afname buizen). Dit betreft een onvoorwaardelijke verstrekking. De firma is niet betrokken bij het design van de studie en zal niet betrokken worden bij de analyse en rapportage van de data.,Maatschappen longziekten en medische microbiologie. Diakademie

(Leerhuis Diakonessenhuis Utrecht). UMC Utrecht (Reguliere salaris onderzoeker AIOS R.W. Hofland)

Intervention

Keyword: Quantiferon, Quantiferon-PLUS, Tuberculosis

Outcome measures

Primary outcome

The differences in QFT-Plus assay results (positive or negative) and the level

of response between the different tubes and different groups

The differences in QFT-Plus assay response during treatment in subjects with

active tuberculosis

Secondary outcome

Other cytokines than interferon gamma enabling to distinguish active TB disease

from latent TB infection

Cell characteristics enabling to distinguish active TB disease from latent TB

infection

Study description

Background summary

Mycobacterium tuberculosis (MTB) still remains a major threat for human health. Diagnosing tuberculosis (TB) is still a challenge and distinguishing active from latent infection can be very difficult. Interferon-gamma release assays (IGRAs) are diagnostic tools for latent tuberculosis infection (LTBI). Two IGRAs are available in many countries: the QuantiFERON-TB Gold assay and the T-SPOT.TB assay.
In 2015, QuantiFERON-TB Gold Plus (QFT-Plus), an updated version of the the QuantiFERON-TB Gold assay, will be introduced by Qiagen. Based on the components, especially the TB-specific CD8+ T cell immunology, this new test possibly might differentiate between latent and active tuberculosis, and might contribute in treatment monitoring. These questions are not studied yet.

Furthermore, except measuring interferon gamma production, this test (QFT-Plus) enables to identify other potential cytokines to distinguish between active TB disease and latent TB infection as well as analyzing functional characteristics of the cells as a potential tool in distinguishing active from latent TB.

Study objective

Primary Objectives:
To explore whether QFT-plus is equipped to differentiate between active TB disease and latent TB infection
To explore a possible correlation between QFT-plus response and time after TB-infection and/or diagnosis tuberculosis / latent tuberculosis infection
To explore QFT-plus kinetics during treatment in patients with active tuberculosis

Secondary Objectives:
To identify other, potential cytokines, enabling to distinguish active TB disease from latent TB infection
To analyze (functional) cell characteristics enabling to distinguish active TB disease from latent TB infection

Study design

Explorative proof of concept study

Study burden and risks

No risks and benefits are expected for participation. All volunteers are asked for a single vena punction, except them treated for active tuberculosis at this moment. They will asked for three more vena punctions during treatment. For all persons, a standard questionnaire and study of medical file for baseline characteristics are completed.

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

Latent or active tuberculosis in history or at this moment

Exclusion criteria

Age < 18 years
Known HIV-infection

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):	24-11-2015
Enrollment:	325
Type:	Actual

Ethics review

Approved WMO Date:	11-08-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-11-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL53628.100.15