Immune responses to an in vivo challenge model using the tuberculin skin test in patients with mycobacterial infections

Published: 09-01-2023
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To determine the relationship between tissue immune responses and the clinical course of mycobacterial infections.

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

Summary

ID

NL-OMON51809

Source
ToetsingOnline

Brief title
MyCoS-TST

Condition

- Mycobacterial infectious disorders

Synonym
Mycobacterial infection

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NIH

Intervention

Keyword: Human challenge models, Mycobacterial infections, Tissue transcriptomics

Outcome measures

Primary outcome

Transcriptional profiling of skin biopsies to determine molecular changes in

immune responses at the site of TST or saline injection.

Secondary outcome

Immunohistopathology of skin biopsies to determine molecular changes in immune

responses at the site of TST or saline injection.

Study description

Background summary

Mycobacterial infections, both tuberculosis (TB) and non-tuberculous mycobacterial infections (NTM), cause over 10 million cases yearly with a wide range of disease manifestations. Treatment is complex, causes considerable toxicity and is hampered by antimicrobial resistance. Therefore, adjunctive therapeutic approaches to improve the treatment of TB and NTM infections are a key research priority. The host immune responses to mycobacterial infections play a vital part in determining the outcome. Immunodeficiency can result in an overwhelming infection due to insufficient control of bacterial replication, while on the other hand, exaggerated inflammatory responses may cause extensive tissue damage and perpetuate disease. Identifying the drivers of these aberrant immune responses using an in vivo model would provide valuable prognostic information as well as a rationale for the use of adjunctive immune-targeting therapies.

Study objective

To determine the relationship between tissue immune responses and the clinical course of mycobacterial infections.

Study design

Observational cohort study.

Study burden and risks

Participation consists of tuberculin skin tests, saline injections, and skin biopsies. There is no clinical benefit to be expected from participation. The burden associated with participation consists of short-term pain or discomfort during injection of the tuberculin / anaesthetic and the possible development of a scar at the injection site. The overall risk of harm is low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Mycobacterial infection

Exclusion criteria

- Known type 1 hypersensitivity to tuberculin PPD RT23 SSI or one of the excipients;
- History of a severe local reaction to tuberculin PPD RT23 SSI or similar products;
- Hypersensitivity to lidocaine or local anaesthetics of the amide type or one of the excipients;
- History of keloid scarring.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2023
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	09-01-2023
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	NL81270.091.22