Non-Tuberculous Mycobacterial Skin and Soft Tissue Infections: Using a Site-of-Disease Approach to Understand Pathophysiology and Improve Outcome

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To identify clinical and immunological parameters that predict the course of disease of non-tuberculous mycobacterial skin and soft tissue infections.

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

Summary

ID

NL-OMON56521

Source
ToetsingOnline

Brief title
MyCoS-SSTI

Condition

- Mycobacterial infectious disorders
- Skin and subcutaneous tissue disorders NEC

Synonym
non-tuberculous mycobacterial skin and soft tissue infections; skin infections caused by mycobacteria

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Endotypes, Immunology, Non-tuberculous mycobacterial infections, Skin and soft tissue infections

Outcome measures

Primary outcome

Transcriptional profiling of skin biopsies to determine the local immune

response to NTM and the changes of the immune response during treatment.

Secondary outcome

Secondary parameters will be:

- Clinical:

o Objective quantification of disease extent (affected area) using medical

photography at baseline, after 8 weeks of treatment, at the moment of treatment

failure (if applicable), and at the end of treatment;

o Histopathology of affected tissue at baseline, after 8 weeks of treatment,

and at the moment of treatment failure (if applicable).

- Microbiological:

o Species determination and antibiotic susceptibility profile;

o Mycobacterial burden at baseline, after 8 weeks of treatment, and at the

moment of treatment failure (if applicable).

- Pharmacological

o Plasma antibiotic levels after 8 weeks of treatment;

o Intracellular antibiotic levels after 8 weeks of treatment;

o Site-of-disease (i.e. skin) antibiotic levels after 8 weeks of treatment.

- Immunological

o Peripheral blood immunological phenotyping at baseline, after 8 weeks of treatment, at the moment of treatment failure (if applicable), and at the end of treatment;

- Patient reported

o Patient reported experience measures (PREM) after 8 weeks, 26 weeks (6 months), and end of treatment;

o Patient reported outcome measures (PROM) after 8 weeks, 26 weeks (6 months), and end of treatment.

Study description

Background summary

Non-tuberculous mycobacteria (NTM) can cause debilitating skin and soft tissue infections (SSTI). NTM SSTI incidence rises with an aged population and increased use of immunosuppression. These infections require 4-6 months of multidrug antibiotic regimens minimally. Still, non-response or worsening of skin lesions occur frequently, because antibiotics fail or too much inflammation occurs. We think that differences in the patients* immune systems, so-called patient endotypes, drive these diverging treatment courses. We currently do not know which immune processes in the skin contribute to these processes. We also lack target concentrations of the key antibiotics azithromycin and clofazimine in the skin, where they need to kill the NTM.

Study objective

To identify clinical and immunological parameters that predict the course of disease of non-tuberculous mycobacterial skin and soft tissue infections.

Study design

Multi-center, observational cohort study.

Study burden and risks

Participation consists of skin biopsies of both affected (6 to 9 biopsies) as non-affected (1 biopsy) tissue and blood sampling. Blood sampling will be conducted during routinely planned venipunctures to minimize the burden. 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 anaesthetic or venipunctures, the extra blood volume drawn, and the possible development of a scar of the biopsy site. The overall risk of participation is low.

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

Non-tuberculous mycobacterial skin and/or soft tissue infection

Exclusion criteria

HIV co-infection
Hypersensitivity to lidocaine, local anaesthetics of the amide type, or one of the excipients
Factors precluding antimycobacterial treatment
Estimated life expectancy < 3 months

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):	21-03-2024
Enrollment:	40
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	20-02-2024

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	NL85356.091.23