Ultra-low-dose computed tomography for latent tuberculosis screening

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23371

Source
NTR

Brief title
ULDTB

Health condition

Latent tuberculosis infection

Sponsors and support

Primary sponsor: not applicable
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

-The proportion of patients with any of various predefined lesions suggestive of old tuberculosis infection detected by ultra low dose CT and chest radiography.

Secondary outcome

- inter-observer variability for latent tuberculosis related lesions on ultra low dose CT as compared to CXR.
- correlation lesions with preventive treatment

Study description

Background summary

A (computed tomography) CT scan has superior sensitivity for old tuberculosis related lesions compared to chest radiography in individuals with latent tuberculosis infection (LTBI), but clinical application of the CT scan in the screening for LTBI is hampered by a high radiation dose. Recently introduced ultra low-dose CT (ULDCT) has much improved diagnostic quality compared to chest radiography but uses a radiation dose comparable to that of a chest radiography.

This study aims to evaluate the diagnostic value of ultra low dose CT for latent tuberculosis. Patients diagnosed with latent tuberculosis will undergo an ultra low dose CT scan as well as a chest radiograph. Subsequently, all images will be scored for LTBI-specific lesions by two thoracic radiologists, independently. Both radiologists are unaware of the TB status of the study patients. We hypothesize that ultra low dose CT has better accuracy for LBTI detection than chest radiography.

Study objective

We hypothesize that the ultra low dose CT reveals significantly more often lesions suggestive for past tuberculosis infection compared to chest radiography

Study design

single visit

Contacts

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Eligibility criteria

Inclusion criteria

All patients diagnosed with latent tuberculosis infection based on a positive tuberculin skin test and/or interferon-gamma release assay

Exclusion criteria

-pregnancy; age < 18yo

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2020
Enrollment:	35
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-12-2020
Application type:	First submission

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
NTR-new	NL9085
Other	METC Leiden Den Haag Delft : P20.036

Study results