Evaluation of ultra low-dose CT for detection of latent tuberculosis

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Primary Objectives:1. To determine the proportion of patients with any of various predefined lesions suggestive of old TB infection detected by ULDCT in patients with LTBI as defined by TST or IGRA result, but without any LTBI-lesions on CXR2. To...

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

Summary

ID

NL-OMON54908

Source
ToetsingOnline

Brief title
Ultra low-dose CT for latent tuberculosis screening

Condition

- Mycobacterial infectious disorders
- Respiratory tract infections

Synonym
latent 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: computed tomography, latent tuberculosis, screening

Outcome measures

Primary outcome

Number of predefined lesions suggestive of old TB infection detected by ULDCT

as compared to chest radiography

Secondary outcome

not applicable

Study description

Background summary

A 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.
We hypothesize that ULDCT has better accuracy for LBTI detection than chest radiography.

Study objective

Primary Objectives:
1. To determine the proportion of patients with any of various predefined lesions suggestive of old TB infection detected by ULDCT in patients with LTBI as defined by TST or IGRA result, but without any LTBI-lesions on CXR
2. To determine which predefined lesions on ULDCT occur at highest frequency in patients with LTBI.

Secondary Objectives:
1. In patients in whom coincidentally a prior CT has been performed: to compare the findings on ULDCT with those on CT
2. To assess inter-observer variability for TB related lesions on ULDCT as compared to CXR.

Study design

Prospective, observational study

Study burden and risks

Ultra low-dose CT examination time itself takes only about 3 seconds. The risks related to the additional ultra low-dose CT-examination consist of additional radiation exposure (approximately 0.07 mSv), which is in the same range as that of a standard chest radiography examination and a factor 50 lower than a standard chest CT examination. The radiation dose is therefore negligible with regard to doses acceptable for research purposes with potential clinical diagnostic gain. The advantages of possible diagnostic outcome of the study, for example better detection of (calcified) nodules, are expected to exceed the risks of radiation-induced complications by far.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with LTBI based on a positive TST and/or QFT result during screening in the past twenty years. Also:
-Age * 18 years
-No LTBI-lesions described in chest radiography (CXR) report during screening for LTBI
-Having given written informed consent prior to undertaking any study-related procedures.

Exclusion criteria

-Pregnancy
-Patients not capable of holding their breath for at least 5 seconds

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2020
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-07-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-02-2021
Application type:	Amendment
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	NL71939.058.19