# Clinical value of ultra-low dose computed tomography compared to chest X-ray investigations in diagnosing pulmonary pathology

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1. To assess the clinical value of ULDCT as compared to CXR examinations for diagnosing pulmonary pathology.2. To identify patient groups or indications that may benefit by replacing CXR by ULDCT examination. 3. To analyze the effect of...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Respiratory tract infections |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON43362

**Source**
ToetsingOnline

**Brief title**
Ultra low-dose CT in diagnosing pulmonary pathology

### Condition

- Respiratory tract infections

**Synonym**
Pulmonary Pathologie

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Radiologie

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** CT, Dose, Pulmonary, ULDCT

## Outcome measures

### Primary outcome

- Percentages of pulmonary pathology detected by ULDCT as compared to CXR.

### Secondary outcome

- Number of patients which have an added clinical value of ULDCT by means of

(potential) changes in clinical decision as compared to CXR examination.

- Analyse the cost-effect when implementing ULDCT instead of CXR.

- To analyse the reconstruction algorithm influence on the clinical detection

probability in ULDCT: AIDR3D versus FIRST

# Study description

### Background summary

The quality of computed tomography (CT) imaging increases and each year more scans are performed in hospitals. However, the radiation dose in CT is of concern because of the potential health hazard of ionizing radiation. Chest-CT uses relatively a high radiation dose (±6 mSv), and is of major importance for the examination and evaluation of chest pathology. However, current developments made it possible to reduce the radiation dose for the patient well maintain the imaging quality by filtered back protection (FBP) and in particular iterative reconstruction (IR) techniques. Several studies have shown that low dose CT and ultra-low dose CT (ULDCT) of the chest is feasible for detecting and characterizing a variety of pulmonary diseases with a radiation dose below one mSv. Furthermore, detection of pulmonary diseases was also feasible with a radiation dose nearly equivalent to chest X-ray (CXR) examination. CXR is the first choice for detecting pulmonary pathology by doctors, because of the high rate radiation dose of standard dose CT (SDCT). However, CXR examination has important diagnostic limitation by being a 2-dimensional projection technique, while CT allows 3-dimensional volumetric

evaluation of the chest. For these reasons ULDCT may replace CXR investigation in evaluating pathology with improved diagnostic quality.

### Study objective

1. To assess the clinical value of ULDCT as compared to CXR examinations for diagnosing pulmonary pathology.
2. To identify patient groups or indications that may benefit by replacing CXR by ULDCT examination.
3. To analyze the effect of reconstruction algorithms on pulmonary pathology in ULDCT: Adaptive Dose Reduction 3D (AIDR3D) versus Forward projected model-based Iterative Reconstruction SoluTion (FIRST).

### Study design

Prospective, observational, intention-to-treat study.

### Study burden and risks

For patients referred for CXR, additional ULDCT examination time takes about 5 minutes.
The risks related to the additional ULDCT-examination consist of additional radiation exposure (< 0.064 mSv), which is in the same range of a standard CXR examination and factor 100 lower than a standard CT examination. The radiation dose is therefore negligible with regard to doses acceptable for research purposes with potential clinical gain. The advantages of possible diagnostic outcome, for example better detection of nodules, of the study are expected to exceed the risks of radiation-induced complications by far.

## 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

* 50 years.
Referral for Chest x-ray.
Having given written informed consent prior to undertaking any study-related procedures.

## Exclusion criteria

BMI * 30.
Patients who are not capable of to hold breath for at least 5 seconds.
Pregnancy.

# Study design

## Design

**Study type:** Observational non invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |

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|---|---|
| Start date (anticipated): | 07-07-2016 |
| Enrollment: | 200 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 29-06-2016 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |
| Approved WMO Date: | 20-07-2016 |
| Application type: | Amendment |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |
| Approved WMO Date: | 20-12-2016 |
| Application type: | Amendment |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

## 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 | NL57546.058.16 |