OPTimal IMAging strategy in patients suspected of non-traumatic pulmonary disease at the ED: Chest X-ray or CT

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Primary objectiveTo evaluate the effects, in terms of patient-related health outcomes and costs, of replacing chest X-ray by ULD chest CT in the diagnostic work-up of patients suspected of non-traumatic pulmonary disease at the ED.Secondary…

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

Summary

ID

NL-OMON45978

Source
ToetsingOnline

Brief title
The OPTIMACT trial

Condition

- Respiratory tract infections

Synonym
non-traumatic pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW doelmatigheidsonderzoek

Intervention

Keyword: chest X-ray, Emergency department, non-traumatic pulmonary disease, ultra-low-dose chest CT

Outcome measures

Primary outcome

- Functional health at 28 days measured by the physical summary scale of the

SF-12.

- Total health care costs during the first 28 days (healt care costs/iPCQ/iMCQ)

Secondary outcome

Secondary study parameters/endpoints are:

- Correct diagnosis at Emergency Department discharge (including use of

other diagnosic measures if indicated), as confirmed by an independent

adjucication committee at day 28.

- Mental health (mental summary scale SF-12)

- Length of hospital stay

- Mortality within 28 days

- Quality Adjusted Life Years during the first 28 days (EQ-5D-5L at 28 days)

- Number of patients in follow-up because of incidental findings on chest

X-ray or ULD chest CT

Additional study parameters/endpoints for CAP sub-study

- Correct diagnosis of CAP at Emergency department discharge, as confirmed by

an independent adjudication committee at day 28

- Initial treatment decision (antibiotics yes/no)

- Total antibiotic use over 28 days

- Aetiology of pneumonia in patients with CAP and correlation of aetiology with

results of chest X-ray and ULD chest CT

- The role of biomarkers in the diagnosis of pneumonia and its

correlation with the correct diagnosis of pneumonia confirmed by an independent

adjudication committee at day 28.

Study description

Background summary

Chest X-ray has been the standard imaging method for patients suspected of non-traumatic pulmonary disease in the Emergency department for years. Recently, ultra-low-dose chest computed tomography (ULD chest CT) has been introduced that provides substantially more detailed information on pulmonary conditions that may cause pulmonary complaints, with a dose in the order of the chest X-ray (0.1 mSv vs 0.05mSv).

This ULD chest CT most likely will lead to more timely diagnoses and improved patient management. Therefore replacement of chest X-ray by ULD chest CT seems a logical step. However, this assumption of more timely diagnoses and improved patient management has not been substantiated. Further, the use of CT leads to higher direct costs and its availability is limited. Importantly, incidental findings on CT lead to additional examinations and associated costs and burden while these findings will be beneficial in only a minority of patients.
Therefore it is necessary to compare both strategies to determine whether it is effective to replace the current diagnostic strategy with chest X-ray for ULD chest CT in patients suspected of non traumatic pulmonary disease at the Emergency department.

Study objective

Primary objective
To evaluate the effects, in terms of patient-related health outcomes and costs, of replacing chest X-ray by ULD chest CT in the diagnostic work-up of patients suspected of non-traumatic pulmonary disease at the ED.

Secondary objective
To evaluatie wether the replacement of chest X-ray by ultra-low-dose chest CT

(ULD chest CT) in the diagnostic work-up of patients suspected of non-traumatic pulmonary disease at the Emergency Department leads to more accurate diagnoses and more timely treatment.
To evaluate, for patients with clinically suspected community-acquired pneumonia (CAP),
- the diagnostic accuracy and clinical impact of performing ultra-low-dose plain chest CT as compared to conventional chest X-ray.
- the accuracy of CT versus conventional X-ray to predict the etiology of the pneumonia.
- the value of new and previously described (molecular) biomarkers for the diagnosis ande etiology of CAP

Study design

A multi-centre, pragmatic, randomized trial comparing chest X-ray to ULD chest CT in patients suspected of non-traumatic pulmonary disease presenting at the Emergency department. As both imaging modalities are considered state-of-the-art, with a radiation dose that is comparable, strategies will rotate randomly per calendar month. Before imaging informed consent will be obtained for participation in the study ans using individual patient data for study purposes.
Embedded in the study is a sub-study for patients suspected of community-acquired pneumonia.

Study burden and risks

RISKS ASSOCIATED WITH PARTICIPATION
Both imaging modalities are considered standard-of-care. Patients who participate in this RCT and will be allocated to the ULD chest CT arm have an associated additional ionizing radiation dose of 0.05 mSV. This is the equivalent of one chest X-rays (0.05 mSv). The collection of three additional tubes of blood totals 11.5 milliliter. This is a very small amount, being less than 1% of the total volume of blood and is therefore not dangerous.

LONG AND SHORT TERM BENEFITS
With ULD chest CT an increase in diagnostic efficiency is expected, which will result in an increase in treatment efficiency, influencing admission policy, hospital stay and recovery of the patient. A side effect of ULD chest CT will be the increase in unexpected findings, especially lung nodules, that will need extra investigations to rule out a serious causes.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-> 18 years,
-presenting at the Emergency department with a suspicion of non-traumatic pulmonary disease: with complaints of: dyspnoea, fever, chest pain or cough.
-written informed consent for data collection

Exclusion criteria

-incapacitated patiënts,
-pregnant patiënts,
-life expectancy less than one month,
-patients with anticipated barriers to completing follow-up data collection,
-patients who are not able to undergo a chest X-ray or chest CT,
-earlier participation in this RCT.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-01-2017
Enrollment:	2400
Type:	Actual

Ethics review

Approved WMO

Date:	24-11-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	22-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	23-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	18-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	27-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26615
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL57923.018.16
OMON	NL-OMON26615