Imaging in Lifelines

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON47260

Source
ToetsingOnline

Brief title
ImaLife

Condition

- Coronary artery disorders
- Respiratory and mediastinal neoplasms malignant and unspecified
- Bronchial disorders (excl neoplasms)

Synonym
coronary heart disease, emphysema, lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: PUSH (Partnership UMCG - Siemens for Healthy Ageing),Siemens

Intervention

Keyword: Biomarker, Cardiovascular Diseases, Chronic Obstructive, Imaging, Lung Neoplasms, Pulmonary Disease

Outcome measures

Primary outcome

Reference values of lung density, bronchial wall thickness, vascular calcification and lung nodules as imaging biomarkers of the Big-3 in the general population aged 45 years and older.

Secondary outcome

Relation of imaging biomarkes of the Big-3 with clinical and laboratory biomarkers.

In the BioLife substudy, CT-nodule characteristics and CT-based emphysema scores are correlated to biomarkers based on breath, nasal brush and blood.

Study description

Background summary

Lung cancer, chronic obstructive pulmonary disease (COPD) and cardiovascular disease (CVD) are prevalent in the general population and are expected to cause most deaths by 2050. For this so-called Big-3, early treatment has been shown to delay or stop progression, and allow therapy at a treatable stage in many patients. A new computed tomography (CT) scan technique can evaluate quantitative imaging biomarkers of early stages of the Big-3 at ultra-low radiation dose. Reference values for imaging biomarkers of early signs of the Big-3 in the general population are lacking. This is the primary purpose of the ImaLife study. This study provides an invaluable resource for the development and validation of biomarker profiles in the context of personalized medicine.

Study objective

The Imalife study aims to assess reference values of lung density, bronchial wall thickness, vascular calcification and lung nodules by quantitative

low-dose CT. Secondarily, it aims to assess the relation of quantitative imaging biomarkers of the Big-3 with clinical and laboratory markers.

Study design

A prospective, single-centre, cross-sectional study. All participants will undergo ultra-low-dose CT scanning.
For the BioLife substudy, individuals with small incidental lung nodules will be asked if they want to participate in a substudy for which they would have to undergo additional collection of blood, a nasal brush and sampling of exhaled breath.

Study burden and risks

Ultra-low-dose CT scans of the heart and lungs will be performed. The total study related radiation dose as calculated by the radiation expert will be between 0.6 and 1.8 mSv, with an additional 0.1 to 1.3 mSv in a subgroup undergoing expiratory CT. These dose ranges fit very well within the radiation dose limits for population imaging as defined by the Gezondheidsraad. The expected risk due to the radiation dose of the CT scan is negligible. There are no adverse events expected during the collection of the CT scans.
In the BioLife substudy venous blood, a nasal brush and sampling of exhaled breath are collected. There are no adverse events expected during the collection of the biomaterials.

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

Participants should be 45 years or older, and have completed a lung function test as part of the second Lifelines screening.

Exclusion criteria

-CT of lungs or heart in the previous year
-known pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-08-2017
Enrollment:	12000
Type:	Actual

Ethics review

Approved WMO Date:	17-03-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-03-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-11-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-03-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL58592.042.16