Ultra-long Field-Of-View Positron Emission Tomography for characterization of indeterminate lung nodules: a pilot study exploring opportunities for clinical research

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In this study, the aim is to derive optimal imaging procedures and to assess the technical performance of the Vision Quadra PET/CT system concerning its feasibility to detect indeterminate lung nodules. Furthermore, this study aims to preliminary...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON51268

Source
ToetsingOnline

Brief title
lung nodule detection using ultra-long FOV PET/CT

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
indeterminate lung nodule, spot on the lung

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: UMCG Kanker Researchfonds

Intervention

Keyword: FDG, lung nodules, Performance evaluation, PET/CT

Outcome measures

Primary outcome

The main study endpoint is a technical performance assessment of lung nodule characterization using the Vision Quadra PET/CT.

Secondary outcome

To develop an optimized long FOV PET/CT imaging procedure (with regard to optimal scan duration and reconstruction parameters) for detection and characterization of indeterminate lung nodules, and to obtain preliminary data on sensitivity, specificity, and accuracy of PET imaging using the Vision Quadra PET/CT for small, indeterminate lung nodules.

Study description

Background summary

Indeterminate lung nodules (6-15 mm) are frequent findings in patients undergoing chest Computed Tomography (CT). In the large randomized controlled Dutch-Belgian lung cancer screening trial NELSON, overall, 9.2% of the screened participants had an initially indeterminate CT scan. To decrease mortality from lung cancer, early identification of malignant lesions among the many lung nodules is crucial. The probability of malignancy depends on size and other factors. It is difficult to determine whether a nodule is malignant on size alone. For further differentiation of a lung nodule, usually, repeated chest CT scanning is performed at 3-6 months up to 2 years to assess nodule growth, and/or 2-deoxy-2-[fluorine-18] fluoro-D-glucose (18F-FDG) Positron Emission Tomography (PET)/CT to evaluate metabolic activity. However, repetitive CT

scans are not favoured because of radiation exposure, patient anxiety, and potential delay in cancer diagnosis. Furthermore, 18F-FDG PET/CT has thus far insufficient sensitivity for detection and characterization of small (in particular < 1 cm) lung nodules, meaning that a negative result does not rule out the presence of cancer, which thus usually requires further follow-up CT scans. Improvement in work-up of indeterminate lung nodules is urgently needed, in particular with the expected introduction of lung cancer screening in the coming years.

Recently, a ground breaking new PET/CT system design was introduced, namely a long total body PET. This system has a greatly improved geometric coverage leading to unprecedented 10 times increased sensitivity compared to current systems. This increased sensitivity can be used to decrease amount of administered radioactivity and/or scan time. Combined with digital technology and excellent time of flight performance, this sensitivity can increase further by a factor of 6.5 (the so-called effective sensitivity). The combination of high spatial resolution and high sensitivity makes total body PET a very promising and potentially ideal non-invasive technique for a more accurate characterization of indeterminate lung nodules without the need to perform long-time follow-up imaging.
In the Netherlands, the first tota body PET, an ultra-long FOV PET/CT scanner manufactured by Siemens, the Siemens Vision Quadra PET/CT system (Siemens Healthineers, Knoxville, TN, USA) will be installed at the UMCG, with expected implementation in Q3 2021.

Study objective

In this study, the aim is to derive optimal imaging procedures and to assess the technical performance of the Vision Quadra PET/CT system concerning its feasibility to detect indeterminate lung nodules. Furthermore, this study aims to preliminary explore the sensitivity, specificity, and accuracy of the characterisation of lung nodules using the Vision Quadra PET/CT.

Study design

After enrolment, patients will receive a standard 3 MBq/kg injection of 18F-FDG and undergo whole-body dynamic PET/CT acquisition at 30-60 min post-injection (pi), followed by a 10 min whole-body list-mode PET/CT acquisition. Subsequently, patients will be asked to hold their breath for 15 seconds to assess the added value of a single fast deep-inspiration breath-hold acquisition. At 120 min pi a second 10 min whole-body list-mode PET/CT will be acquired to potentially further differentiate between inflammation and malignancy.
The list-mode acquisitions can be reprocessed retrospectively with less counts to produce images representing scans collected with lower activity administration or shorter scan times (e.g., a 1 min instead of 10 min PET scan

is equivalent to 10% of the injected activity at scan start). Pharmacokinetic, semi-quantitative (SUVmax and SUVpeak) and subjective qualitative image analysis will be correlated with pathology (benign or malignant) of the lung lesion, and results of a previously performed routine-care 18F-FDG PET/CT and CT chest.

Intervention

Intravenous injection of radioactive 18F-FDG

Study burden and risks

Patients will receive a single standard injection of 18F-FDG followed by two imaging procedures, i.e., two whole-body 18F-FDG PET/CT scans, each preceded by a low-dose CT for attenuation correction (radiation exposure approximately 1.5 mSv). The PET effective dose using a single injection of 18F-FDG activity is approximately 4 mSv. In total the effective dose participants will receive is: 4 + 2x1.5 = 7 mSv.

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

18 years or older
able to give informed consent
signed informed consent
confirmed indeterminate lung nodule(s) of 6-15 mm in size on CT chest imaging
routine [18]F-FDG PET/CT
scheduled for biopsy or surgical removal of the lung nodule(s)

Exclusion criteria

claustrophobic
pregnant or breastfeeding women
interval of at least 2 weeks between PET scan and last date of systemic anti-cancer therapy
radiation therapy of the target lung nodule(s)
uncontrolled diabetes mellitus
any medical condition potentially hampering conduction of the trial

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-07-2022

Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Biograph Vision Quadra PET/CT
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	(18)F-fluorodeoxyglucose (FDG)
Generic name:	18F-FDG

Ethics review

Approved WMO Date:	23-12-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-01-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-06-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-05-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-12-2024
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
EudraCT	EUCTR2021-005318-32-NL
CCMO	NL77036.042.21