Intra-individual patient-based comparison of conventional and digital PET/CT scanners

Published: 01-06-2015
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Primary: How does the diagnostic outcome of the digital PET/CT study compare to the outcome of conventional PET/CT in patients referred for (re)staging of lung cancer, breast cancer and a group of miscellaneous cancers?Secundary: What is the image...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON46943

Source
ToetsingOnline

Brief title
Comparison of conventional and digital PET/CT

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, oncology

Research involving
Human

Sponsors and support

Primary sponsor: Isala, Zwolle
Source(s) of monetary or material Support: Philips Healthcare

Intervention

Keyword: FDG, oncology, PET/CT, staging

Outcome measures

Primary outcome

Final result of the PET/CT study. This outcome parameter includes multiple parameters, such as the number of regional lymph nodes, the number of distant metastasis and the final TNM classification.

Secondary outcome

PET image quality. This outcome parameter includes multiple parameters, such as the image noise, diagnostic confidence and lesion detectability (contrast-to-noise etc.).

Study description

Background summary

FDG-PET/CT imaging is important for staging, response monitoring and prognosis prediction in patients with cancer. However, the spatial resolution of current PET/CT systems is relatively low, limiting the detection of small lesions and accurate staging. In 2017, a very novel state-of-the-art digital PET/CT system will be installed at the NM department in Isala. It is expected that this new type of scanner contributes to more accurate staging and possibly more effective patient management. For a period of 6-12 months, both a conventional and a digital PET/CT system will be available in the NM department in Isala. This provides the unique possibility to evaluate the performance of the digital PET/CT system compared with conventional PET/CT. In this study, we will analyze the impact of digital PET/CT on the final diagnostic conclusion of the scan in patients with lung cancer, breast cancer and a group of miscellaneous cancers.

Study objective

Primary: How does the diagnostic outcome of the digital PET/CT study compare to the outcome of conventional PET/CT in patients referred for (re)staging of lung cancer, breast cancer and a group of miscellaneous cancers?

Secundary: What is the image quality (in both quantitative and qualitative terms) of digital PET as compared to conventional PET?

Study design

Single center diagnostic accuracy study

Intervention

not applicable

Study burden and risks

*Additional scan time: Immediately after acquisition of the first clinical PET/CT study, a second PET/CT study will be obtained. The additional time in the second PET/CT scanner will typically be 25 minutes (maximum 40 minutes), in which patients have to lie still on a scanner bed.

*Additional radiation dose: In a standard clinical FDG-PET/CT scan, the average dose is 14 milliSievert (mSv). This consists of the dose from a low-dose CT scan for attenuation-correction and the dose from FDG. In several cases, an additional CT-scan with intravenous contrast is acquired for diagnostic purposes, leading to a total radiation dose of averagely 22 mSv. In comparison: the extra study-related low-dose CT scan will give an additional radiation dose of on average 6 mSv. The total dose is body-weight dependent.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* referred for a clinically indicated FDG-PET/CT scan
* suspected or proven lung cancer, breast cancer and a group of miscellaneous cancers
* signed informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* age < 18 years
* incapacitated adults
* prisoners
* pregnant woman
* not able to undergo two consecutive PET/CT scans

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):	13-11-2017
Enrollment:	225
Type:	Anticipated

Ethics review

Approved WMO Date:	01-06-2015
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-11-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	27-02-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL52329.075.15