PET/CT Robustness In Melanoma

Published: 26-03-2020
Last updated: 10-04-2024

Determining the robustness of [18F]-FDG PET/CT based quantitative features in metastatic melanoma patients by test-retesting [18F]-FDG PET/CT scans and varying post processing scan settings, for future diagnostic and prognostic clinical application...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON48328

Source
ToetsingOnline

Brief title
PRIME

Condition

- Skin neoplasms malignant and unspecified

Synonym
Melanoma, mole cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Investigator initiated study: geldstroom via eigen afdeling Nucleaire Geneeskunde binnen het NKI-AVL.

Intervention

Keyword: FDG, imaging, melanoma, PET

Outcome measures

Primary outcome

The main study parameter is the variation in [18F]-FDG PET/CT quantification features between the test and retest scan.

Secondary outcome

Our secondary endpoints are the variation between post processing settings on the quantitative [18F]-FDG PET/CT features within scans. As quality control quantitative [18F]-FDG PET/CT features will also be measured on normal organ tissue. The amount of tumour lesions and their size will be measured.

Study description

Background summary

The incidence of melanoma is rising in the Netherlands and worldwide, with current death rates of 800 patients per year in the Netherlands. Once metastasized, death has historically been imminent for patients, until the emergence of targeted- and immunotherapy. With response rates of 6-59% and 5-year survival rates reaching 40-50% from a prior 10%, a new era has begun (1). However, as the variety in response rates signifies, a sizeable percentage of patients do not respond and it is unclear if all lesions within a patient respond similarly. Inter- and intra-tumour heterogeneity could be a contributing factor to response failure (2,3). Characterising each tumour lesion translates into biopsying each individual lesion leading to excessive patient burden. PET/CT imaging provides the ability to visualize all lesions on both an anatomical and functional basis. Adding PET/CT quantification analysis, an unique and extensive non-invasive characterisation of all tumour lesions can be provided. Until now only dermoscopy, confocal microscopy and CT based quantification have been used in melanoma for diagnostic and prognostic model building with promising results (4,5). One of the main challenges of imaging based quantification research is the robustness of features, i.e. their variability over time and susceptibility to different scan settings. No studies have been performed to assess feature robustness in melanoma PET/CT quantification, which is vital as a primary step to determine which features are best to use in a predictive model for clinical application.

Study objective

Determining the robustness of [18F]-FDG PET/CT based quantitative features in metastatic melanoma patients by test-retesting [18F]-FDG PET/CT scans and varying post processing scan settings, for future diagnostic and prognostic clinical application.

Study design

This is a monocenter non-randomised prospective observational study, for a duration of 1 year. The main procedure consists of repeating a [18F]-FDG PET/CT scan *1 < 7 days of a first clinically indicated scan, all according to standard clinical protocol. Addition of a variation in the post-processing settings will be added after the patient has already left the scanner. 28 evaluable patients will be included of which a patient will be replaced if one withdraws or is withdrawn from the study. A schedule for one patient is as follows:

Day 1: [18F]-FDG PET/CT scan as planned (=test scan, clinically indicated)
Day 3, 4, 5, 6 or 7: [18F]-FDG PET/CT scan (=retest scan, additional scan for study purposes)

Study burden and risks

Not applicable. There is minimal patient burden consisting of one extra hospital visit of 1.5 hours for one additional [18F]-FDG PET scan with an additional radiation dose of ±9 mSv.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. *18 years old
2. Histopathologically confirmed melanoma
3. Clinical stage IIIB/C/D, IV melanoma
4. Scheduled for a routine baseline [18F]-FDG PET/CT scan
5. Minimal one lesion with longest diameter * 20 mm
6. WHO performance status * 2
7. Ability to undergo the scan in supine position
8. Capacity to give informed consent

Exclusion criteria

1. Pregnant
2. Breast feeding
3. Claustrophobia
4. Confirmed diabetes mellitus I or II
5. Body weight >100 kg
6. Metal implants/prostheses, evaluated by study team
7. No systemic therapy (chemotherapy, immunotherapy, targeted therapy) 3 months prior to scan

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-12-2021
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	26-03-2020
Application type:	First submission
Review commission:	METC NedMec

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	NL72146.031.19