Additional value of 18F-FDG PET-MRI in patients with melanoma

Published: 29-11-2021
Last updated: 04-04-2024

Primary Objectives- To investigate the impact of dose reduction of 18F-FDG on image quality of PET-MRII in patients with melanoma. Secondary Objectives- To determine the maximum reduction of radiation dose for 18F-FDG PET-MRI as compared to...

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

Summary

ID

NL-OMON50805

Source
ToetsingOnline

Brief title
18F-FDG PET-MRI bij melanoom

Condition

- Skin neoplasms malignant and unspecified

Synonym
melanoma, skin cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 18F-FDG, Melanoma, PET-MRI

Outcome measures

Primary outcome

Image analysis for primary endpoint, i.e image quality:

- Image quality will be scored on a 4-point scale according to Halpern et al (34) ranging from 0 to 3: 0 (non-diagnostic), 1 (poor), 2 (moderate) and 3 (good).

- Lesion detectability between reconstructions will be evaluated by counting the number of 18F-FDG positive lesions per body region (head/neck, thorax, abdomen, soft tissue of extremities and skeleton) according to different reconstructions. The lesions will be categorized as follows: 0 lesions (0), 1 lesion (1), 2 lesions (2), 3-5 lesions (3), 6-10 lesions (4) and >10 lesions (5).

Secondary outcome

Image analysis for secondary endpoints, i.e. diagnostic performance:

Diagnostic performances of the 4 index tests (18F-FDG PET/MRI, 18F-FDG PET-CT, contrast enhanced CT and TB MRI) will be measured on a per-patient level. Sensitivity, specificity, PPV and NPV will be calculated based on the per-patient outcomes (0 or >=1 metastasis).

Number of metastases will be counted per-patient and will be categorized as follows: 0 metastasis (0), 1-5 metastases (1), and > 5 metastases (2).

Study description

Background summary

Melanoma is an aggressive form of skin cancer and is responsible for most skin related deaths (1). In Europe, the incidence rates between 1995 and 2012 increased significantly for both men and women. In particular, the Netherlands showed a remarkable increase in incidence rate. As a result, an increase in mortality has been reported . However, in the past decade, considerable progress has been made in the treatment of metastatic melanoma .

New therapies such as immunotherapy (immune checkpoint inhibitors) and targeted therapy (BRAF/MEK-inhibitors) have shown considerable survival benefits (1). Immune checkpoint inhibitors can induce durable tumor responses up to 10 years or even longer. As a result, patients with advanced melanoma are subjected to a long follow-up period (10 years) after discontinuation of treatment.

For early detection of recurrent or progressive disease, a contrast enhanced computed tomography (CT) is usually performed every 3 months and this interval can be increased every year thereafter. Depending on local institutional guidelines, contrast enhanced CT is combined with positron emission tomography (PET) using fluor-18 fluorodeoxyglucose positron emission tomography (18F-FDG PET). However, these imaging techniques are associated with radiation exposure. The average radiation exposure caused by one contrast enhanced CT-scan of the thorax and abdomen is 8.4 millisievert (mSv). In addition, the average radiation exposure caused by 18F-FDG (3.3 mSv) for PET with a low-dose CT (3.1 mSv) is 6.4 mSv.

Study objective

Primary Objectives
- To investigate the impact of dose reduction of 18F-FDG on image quality of PET-MRII in patients with melanoma.

Secondary Objectives
- To determine the maximum reduction of radiation dose for 18F-FDG PET-MRI as compared to contrast enhanced CT and 18F-FDG PET-CT.
- To determine the diagnostic performance of PET-MRI using a reduced dose of 18F-FDG in patients with advanced melanoma
- To compare the diagnostic performance of PET-MRI using a reduced dose of 18F-FDG with 18F-FDG PET-CT, contrast enhanced CT and TB MRI.

Study design

This is a prospective, explorative study in patients with melanoma.

Study burden and risks

Patients with melanoma who are referred for routine 18F-FDG PET/CT will be asked to undergo an additional PET-MRI with administration of gadolinium contrast agent on the same day. After injection of 18F-FDG and image acquisition using PET-CT, patients will undergo PET-MRI. For PET-MRI, there will be no additional radiation exposure, as 18F-FDG will be administered once (prior to PET-CT). Gadolinium contrast agent will be dosed according to local guidelines (one bolus of 7.5 cc gadobutrol 1,0 mmol/ml (Gadovist*)).

Additional PET-CT scan will require the patients to lay still in the PET-MRI scanner for approximately 60 minutes which may cause discomfort for the patients.

Gadolinium may cause contrast agent related reaction(s). However, an up-to-date protocol has been prepared by our institute on how to handle if contrast agent related reaction(s) appear.

Considering the potential benefit of this study for future follow-up of patients with melanoma, the additional imaging with PET-MRI is considered justified.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

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:
- Histopathological proven melanoma for which 18F-FDG PET-CT is indicated. For example, patients in follow-up or under treatment can be included.
- Referral for 18F-FDG PET-CT at Erasmus MC
- Signed informed consent
- Age >= 18 years
- Willing to undergo additional PET-MRI

Exclusion criteria

- Contra-indications to undergo MRI:
o Pacemaker, mechanic heart valve, blood vessel prosthetic, stent or coil
o Metal in eyes (splinters, from surgery), ears (hearing aid) or on the body where it cannot be removed (insulin pump, piercings etc.)
o Dental prosthesis with magnetic system
o Claustrophobia
- Pregnancy or breastfeeding
- Allergy to contrast agent containing gadolinium

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2021
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	PET-MRI scanner
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-11-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL76024.078.21