Novel Ga68-PSMA PET-tracer to differentiate between radiation necrosis and tumor progression in stereotactic irradiated brain metastases. A feasibility study.

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In this study we will investigate whether there is a difference in PSMA expression between BM and RN by:1. Evaluating PSMA expression using Ga68-PSMA PET/CT in BM of NSCLC, melanoma and breastcancer patients eligible for SRT or surgery.2. Evaluating...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON54566

Source
ToetsingOnline

Brief title
Ga68-PSMA in brain metastases

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain metastases, breast cancer, lungcancer, melanoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brain Metastases, Breast cancer, Ga68-PSMA PET, Melanoma, Non-small cell lung cancer

Outcome measures

Primary outcome

For group 1, 2 and 7 the sensitivity (ability of the test to correctly identify those patients with the disease) of the Ga68-PSMA brain imaging will be determined.

For group 3, 4 and 8 the specificity (the ability of the test to correctly diagnose those patients without the disease) of the Ga68-PSMA brain imaging will be determined.

In case the study for research question 1 shows Ga68-PSMA uptake in 70% of the cases, we can continue studying research question 2.

In case there is no or a low Ga68-PSMA uptake in the patients with RN (research question 2), we will continue with the study in patients with irradiated BM, in whom there is a true dilemma whether there is RN or tumor progression (research question 3).

For group 5, 6 and 9, the sensitivity and specificity will be determined.

In case Ga68-PSMA brain imaging can diagnose in RN vs tumor progression in 7 of 10 patients (per tumor type) in a correct way, a future clinical diagnostic

study with higher patient numbers will be initiated.

Secondary outcome

na

Study description

Background summary

After SRT, the national guidelines advise to execute a 3- monthly MRI-brain evaluation to screen for recurrent (local and/or distant) BM. During MRI follow-up, irradiated lesions can increase in size or edema, which could be due to either radiation necrosis (RN) or tumor progression.
With the original MRI sequences (T1 -/+ contrast, T2 and diffusion), and 18-FDG PET CT imaging, it is not possible to make a reliable distinction between RN and tumor progression. Reliable distinction is important for correctly initiating new tumor therapy. Ga68-PSMA tracer is a novel PET tracer and has high potential in reliably differentiate between RN and tumor progression.

Study objective

In this study we will investigate whether there is a difference in PSMA expression between BM and RN by:
1. Evaluating PSMA expression using Ga68-PSMA PET/CT in BM of NSCLC, melanoma and breastcancer patients eligible for SRT or surgery.
2. Evaluating PSMA expression using Ga68-PSMA PET/CT in patients with definite RN.
3. Evaluating the use of Ga68-PSMA PET/CT to differentiate progressive BM of NSCLC, melanoma or breastcancer from radiation necrosis by quantifying PSMA.

Study design

a diagnostic feasibility study

Study burden and risks

The burden and risks associated with participation are considered low. After SRT, MRI of the brain are part of the routine diagnostic follow up. Use of positron emitting radionuclides means exposure to ionizing radiation. The radiation exposure will be 2,0 mSv in total per patient. Extra time for the patient is 90 minutes for the PET CT scan. The long term risk of developing a secondary malignancy due to radiation exposure is theorethical, because of the

limited life expectancy of patients with BM in NSCLC, melanoma and breastcancer. Since there is a lack of a reliable diagnostic imaging for differentiation between RN and tumorprogression, the results of this study can be of high interest for BM patients, in whom during follow up the diagnostic dilemma occurs.

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

For group 1, 2 and 7: - newly diagnosed BM from either NSCLC (group 1), melanoma (group 2) and breast cancer (group 7) For group 3, 4 and 8: - Brain lesion at the location of a formerly BM that has been treated with SRT (> 9 months ago), with the definite diagnosis of RN at the location of formerly SRT-treated BM of NSCLC (group 3), melanoma (group 4) and breast cancer (group

8). For group 5, 6 and 9: - Brain lesion at the location of a formerly BM in which the diagnostic dilemma of RN and recurrent BM of NSCLC (group 5), melanoma (group 6) or breast cancer (group 9).

Exclusion criteria

For all groups: - Allergy to Ga68-PSMA - Epileptic seizure < 7 days before Ga68-PSMA PET/CT scan - Life expectancy less than 3 months - Patients with prostate carcinoma

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):	24-12-2019
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	22-07-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	18-03-2020
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	26-11-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-05-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-07-2023
Application type:	Amendment
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	NL66822.031.19