Non-invasive axillary lymph node staging in breast cancer with PET/MRI

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON54725

Source
ToetsingOnline

Brief title
PET/MRI in node negative breast cancer

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast cancer, Node negative, PET/MRI

Outcome measures

Primary outcome

The accuracy (sensitivity, specificity, PPV, NPV, FNR) of dedicated axillary hybrid PET/MRI versus pathological outcome of SLNB will be investigated. The accuracy of PET/MRI will be determined on the basis of node-by-node matching of the imaged nodes to the pathological outcome of SLNB and patient-by-patient analysis.

Secondary outcome

To investigate the diagnostic value of the three MRI sequences (T2w, DWI and hybrid PET/MRI) using a dedicated axillary unenhanced hybrid PET/MRI protocol.

Study description

Background summary

Axillary lymph node status is an important prognostic factor for patients with breast cancer. After breast cancer diagnosis, current nodal staging consists of axillary ultrasound (US) combined with tissue sampling when deemed necessary. In case of positive axillary lymph nodes, patients will undergo axillary lymph node dissection (ALND). In case of no suspicious axillary lymph nodes (i.e. clinically node negative patients), patients will undergo sentinel lymph node biopsy (SLNB). This surgical nodal staging is accompanied by co-morbidity. In theory, if non-invasive imaging can evaluate the lymph node status accurately, a node negative patient would no longer have to undergo axillary surgery. Since MRI is suitable for soft tissue imaging and PET has the advantage of showing increased metabolic uptale in lymph node metastases, a combination of these techniques in hybrid PET/MRI would be highly desirable. If dedicated axillary hybrid PET/MRI is equally accurate to SLNB for the detection of negative axillary lymph nodes, work-up could be more efficient by bypassing SLNB. However, the accuracy of dedicated axillary hybrid PET/MRI needs to be compared

with the pathological outcome of SLNB (gold standard) first.

Study objective

The main goal of this study is to study the accuracy (sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and false negative rate (FNR)) of dedicated axillary hybrid PET/MRI for the detection of negative axillary lymph nodes in breast cancer patients. The accuracy of PET/MRI will be compared with the pathological outcome of SLNB.

Study design

The study is designed as a multi center prospective cohort study.

Intervention

If a patient provides informed consent, she will undergo a PET/MRI with dedicated axillary coil before surgical staging. As contrast agent the radioactive tracer 18F-FDG will be used (no gadolinium-based MRI contrast agents). We will integrate this study in the regular treatment of the patient, causing no delay in their treatment plan.

Study burden and risks

The patient who participates in this study will undergo regular investigations of nodal staging in breast cancer. For this study we will perform an extra PET/MRI of the axilla before the surgical staging. Furthermore, the lymphoscintigraphy will be supplemented with a SPECT/CT scan for the node-by-node matching. All further procedures are already included in the regular treatment. Patients participating in this study do not directly benefit themselves, but can help prevent future patients with negative axillary lymph nodes from undergoing axillary surgery.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Female patient with histologically confirmed breast cancer and clinically confirmed negative lymph nodes in the axilla, scheduled to undergo SLNB
2. Patients who are willing and able to undergo the study procedures
3. The patient has provided personally written informed consent

Exclusion criteria

1. Patients treated with neoadjuvant systemic therapy prior to axillary nodal staging
2. Patients with clinically positive axillary lymph nodes
3. Age < 18 years
4. Inability to provide informed consent
5. Pregnancy
6. Weight >100 kg (because of the format of the PET/MRI scanner)
7. General contraindications for MRI (such as pacemaker, aneurysm clips, metallic device in their body, severe claustrophobia) or PET (i.e. known allergy to 18F-FDG)
8. Hyperglycaemia (> 11 mmol/L) at the time of 18F-FDG injection

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):	24-05-2018
Enrollment:	125
Type:	Actual

Ethics review

Approved WMO Date:	04-10-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-12-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-07-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL62441.068.17