Supine MRI-guided navigation for tumor localization in breast cancer patients: a feasibility study.

Published: 12-10-2016
Last updated: 14-04-2024

Primary goal: to assess the accuracy of a supine magnetic resonance imaging (MRI)-guided electromagnetic navigation system used for tumor marker implantation in breast cancer patients.Secondary goal: to assess the variability in target volume...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON43198

Source
ToetsingOnline

Brief title
MRI-guided navigation for tumor localization in breast cancer patients.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

Synonym
Invasive breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NKI-AvL

Intervention

Keyword: Breast cancer, Electromagnetism, Image-guided navigation, Supine MRI

Outcome measures

Primary outcome

The primary outcome of the study is the accuracy of the supine MRI-guided navigated tumor marker implantation. The accuracy is defined as the difference between planned marker location on supine MRI and actual marker location as seen on CT which is acquired after the implantation procedure.

Secondary outcome

The secondary outcome of the study is the variability in target volume delineations on pre-operative supine CT with that of registered supine CT-MR scans. The variability is defined as the difference in standard deviation on the surface distance maps between the delineations made on CT only compared to that of registered MR-CT.

Study description

Background summary

A typical treatment for women with breast cancer is breast-conserving surgery (BCS) followed by radiotherapy (RT), providing good survival rates. In order to remove all tumor tissue during BCS, adequate tumor localization is essential. Current localization procedures typically use a marker that is implanted in the center of the tumor under ultrasonography (US) or stereotactic mammography (XM) guidance. However, for patients with non-palpable or diffuse breast cancer it would be beneficial to not implant one marker in the center, but multiple markers at the borders of the tumor. Currently, tumor marker implantation is prepared by assessment of prior-obtained imaging data, usually a combination of mammography, ultrasound and contrast-enhanced MRI (CE-MRI). However, all imaging data are acquired with the patient in another position than during the marker implantation procedure and BCS when the patient is lying in supine

position. Secondly, tumor location and extent as seen on the imaging data is not translated to the patients* anatomy of that day during implantation or surgery.

Recently, supine breast MRI with an image quality comparable to diagnostic prone CE-MRI has become available in our hospital. Firstly, supine MRI images the breast in the identical patient setup as during marker implantation and BCS. Secondly, a navigation system can be used to link the pre-obtained supine MRI to the patient position during the implantation procedure and BCS. Such a system is capable of visualizing the tumor as seen on the supine MRI with respect to the patients* anatomy of that day. This is the first feasibility study to assess the accuracy of marker implantation based on supine MRI and by using such a navigation system.

Study objective

Primary goal:
to assess the accuracy of a supine magnetic resonance imaging (MRI)-guided electromagnetic navigation system used for tumor marker implantation in breast cancer patients.

Secondary goal:
to assess the variability in target volume delineations on pre-operative CT and registered CT-supine MRI between different radiation oncologists.

Study design

Informed consent will be obtained during the outpatient clinic appointment. On the same day as the scheduled tumor marker implantation, a contrast-enhanced MRI in supine position is acquired. Before acquisition of the MRI, five reference markers are placed on the skin of the affected breast. Locations of these markers is drawn on the skin of the patient using a permanent marker. The reference markers will be visible on the supine MRI. Afterwards, tumor delineation and the desired target point of the tumor marker is determined on the supine MRI by the researcher and the radiologist.

Before the implantation procedure starts, the supine MRI with the corresponding tumor delineation and marker target point is loaded into the navigation software. An electromagnetic (EM) field generator (Aurora) is placed near the table where the marker implantation will occur. Subsequently, the generator is switched on in order to generate an EM field in the proximity of the patient table. An electromagnetic (EM) reference sensor is attached to the implantation needle in order to track the needle in the presence of the EM-field. After the patient is positioned on the table, a point registration is performed using the tracked needle between the reference markers on the supine MRI and on the corresponding location of the markers on the skin of the patient.

During the marker implantation, the tracked needle is visualized with respect to the tumor delineation and the corresponding target point on the supine MRI by the navigation software. Before the needle is inserted into the breast, the correct anatomical location is confirmed by ultrasonography (US). The correct target point inside the breast is also verified with US before release of the marker in the tumor.

After the implantation procedure, a mammography is performed according to standard clinical practice. Additionally, a CT without contrast is acquired.

Intervention

On the day of the marker implantation, a supine contrast-enhanced (CE) MRI is acquired.
After the implantation procedure, a CT without contrast agent is acquired.

Study burden and risks

The additional burden for the patient consists of a supine MRI with administration of contrast agent (gadolinium). The risks for an allergic reaction are small since only patients will be included that underwent a contrast-enhanced MRI in prone position before. Furthermore, a CT without contrast agent will be acquired. The radiation load of this scan is negligible since these patients will all undergo post-operative radiation. We estimate that the image-guided navigated marker implantation will take 15 minutes longer than the conventional marker implantation procedure.

Furthermore, the first 5 patients will undergo marker implantation accordingly current clinical practice (using ultrasound-guidance). However, the implantation procedure is prepared accordingly the new workflow including acquisition of the supine MRI, tumor delineation and determination of target point, registration of the supine MRI with physical space etc. In this manner, the radiologist can get familiar with the new workflow and the viewing station without the risk of delaying the procedure in the first included patients.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL

Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patients with an invasive breast carcinoma, visible on prone CE-MRI.
• Patients who are scheduled for single-seed RSL.
• A signed informed consent.
• Patients >= 18 years old.

Exclusion criteria

• Contraindication for MRI in supine position or CT.
• Contraindication for gadolinium contrast administration.

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	13-04-2017
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	NL57876.031.16