Quality improvement project evaluating the impact of preoperative MRI on the reduction of positive histological margins and reoperations in patients eligible for breast conserving therapy

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Determine if additional pre-operative MRI decreases the incidence of irradical lumpectomies, changes surgical planning for BCT, reduces the incidence of re-operations, increases sensitivity and/or specificity, and is cost-effective.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON30682

Source ToetsingOnline

Brief title Preoperative MRI in patients with breast cancer

Condition

Other condition

Synonym Breast cancer

Health condition

diagnostisch onderzoek met als doel tot een optimale planning voor borstsparende chirurgie te komen voor patiënten met mammacarcinoom

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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: Breast conserving therapy, Breastcancer, Magnetic Resonance Imaging (MRI), Mammography

Outcome measures

Primary outcome

Reduction of irradical lumpectomies

The primary goal of additional preoperative imaging and discussion is to reduce the rate of irradical lumpectomies. The histology reports of the specimen will be the reference standard. Assessment of irradicallity will be judged according to national guidelines. The percentage of lumpectomy specimens with positive margins will be documented and compared to that in the historical control group.

Secondary outcome

- Reduction of re-operations

The number and percentage of re-operations will be documented and compared to that in the historical control group.

Accuracy of tumor size estimation

Histology reports of the specimens of all patients will be compared with the outcomes of clinical examination and breast imaging with and without MRI in

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order to assess extent of tumor and size in mm*s. Correlation coefficients versus histology (as reference standard) will be calculated for the sizes determined by conventional workup and by MRI.

- Sensitivity and specificity of the imaging modalities in diagnosing tumor size and extent

Histology (as reference standard) of the specimens of all patients will be compared with the outcomes of breast imaging with and without MRI in order to assess sensitivity and specificity of the imaging modalities, and especially MRI, in diagnosing size and extent of the tumor.

- Cost-effectiveness of preoperative MRI

Finally, a cost-effectiveness analysis of preoperative MRI will be performed,

taking into account the costs of clinical examination, the preoperative imaging

procedures, the costs of the initial surgical procedures and re-operations, and

the effectiveness of radical versus irradical treatment.

Study description

Background summary

Breast conservation therapy (BCT) is an appropriate and cosmetically preferable alternative to mastectomy for early-stage invasive breast cancers as well as ductal carcinoma in situ (DCIS). BCT requires complete removal of all tumor, necessitating histologically negative margins to decrease the risk of local recurrence. In case of close or positive margins re-excision or mastectomy will be performed to achieve a radical excision. Therefore, patients eligible for breast conserving therapy may require more than one operation. Accurate preoperative assessment of tumor size and disease extent is essential

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for surgical planning. Clinical examination, mammography and ultrasound are the standard techniques to assess tumor extent. However, clinical examination correlates poorly with histology; mammography tends to underestimate tumor size and focality; and ultrasound is limited in the detection of multifocality and ductal carcinoma in situ (DCIS). Magnetic Resonance Imaging (MRI) has a high sensitivity, correlates well with histology, and gives an accurate estimate of tumor size and focality in most cases. We propose that preoperative MRI of the breast will provide surgeons with more accurate information about tumor size and position, resulting in a lower percentage of positive margins and thus of re-operation.

Study objective

Determine if additional pre-operative MRI decreases the incidence of irradical lumpectomies, changes surgical planning for BCT, reduces the incidence of re-operations, increases sensitivity and/or specificity, and is cost-effective.

Study design

Historically-controlled cohort study.

Study burden and risks

Subjects will undergo a single MRI scan, with contrast, in addition to the normal pre-operative work-up. MRI of the breast is a non-invasive, safe technique with little patient discomfort. If indicated an extra ultrasound examination will be performed, with biopsy if necessary. The subjects will benefit from a more thorough diagnostic work-up and more informed surgical planning than they would receive without participation. This trial should result in information to improve the quality of the diagnostic work-up of BCT patients as well as being a vessel for the implementation of a new and better diagnostic work-up, if this is warranted.

Contacts

Public Erasmus MC, Universitair Medisch Centrum Rotterdam

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- breast cancer patients eligible for breast conserving therapy
- signed informed consent

Exclusion criteria

- contra-indications for MRI
- pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:

Diagnostic

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2007
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO	
Date:	15-03-2007
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 CCMO **ID** NL15262.078.06