Minimal invasive Microwave Ablation in early stage breaST cancER, a feasibility study

Published: 19-01-2023
Last updated: 30-01-2025

To assess whether minimally invasive nonsurgical microwave ablation (MWA) followed by postprocedural MRI scan can be an alternative treatment for breast surgery in early stage breast cancer: a non-inferiority study .Is the quality of life, cosmetic...

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

Summary

ID

NL-OMON51501

Source
ToetsingOnline

Brief title
MASTER study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Early stage breast cancer (stage 1)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Johnson&Johnson,UMCG kankerresearchfonds

Intervention

Keyword: Breast cancer, Breast MRI scan, Cost-effectiveness, Microwave ablation

Outcome measures

Primary outcome

Minimally invasive nonsurgical MWA followed by postprocedural DCE-MRI scan in patients with early stage breast cancer is a safe and effectiveness alternative for breast surgery.

Secondary outcome

The quality of life, cosmetic outcome in patients treated with MWA will be non-inferior to those in patients treated with standard care, where the costs will be lower and the fear for breast cancer recurrence will be equal.

Study description

Background summary

In the Netherlands approximately one out of seven women will develop breast cancer during her life [1]. Most of these breast cancers are early stage, 40% of the women have stage 1 [2]. Stage 1 breast cancer means that the cancer is small (size <2cm) and only in the breast tissue or it might be found in lymph nodes close to the breast [3]. The standard treatment for stage 1 breast cancer is breast conserving surgery (BCS), sentinel lymph node procedure (SLNP) and additional radiotherapy [4]. When BCS is performed, pathologic evaluation of the margins is required, because residual (in situ) breast cancer in the resection margins is the most important predictive factor for local recurrence. Between 11% and 30% re-excisions are performed after BCS, which can result in a poor cosmetic outcome, higher burden for the patient, sometimes conversion to mastectomy and higher health care costs [5-8]. This standard treatment protocol results in a10 years survival rate of 95% for stage 1 disease [3]. However, nowadays there is a discussion whether these early stage breast cancer could be treated less invasively[10-14].
To reduce the invasiveness of breast cancer treatment, without compromising breast cancer specific survival, minimally invasive nonsurgical ablation procedures of breast cancer have been investigated for small breast lesions

[15-19]. Ablation of the tumor can be achieved by using extreme hyperthermia to destroy the tumor cells. This ablation technique can ablate an area up to 3 cm with a single probe. This is one of the reason that this technique is suitable for the treatment of breast tumors<2 cm, because a margin of 0.5-1.0 cm should be included in the ablation volume [20]. Furthermore, there are several advantages of ablation procedures: it is a minimal invasive technique, with a small or absent cutaneous scar and thereby potentially improving patient quality of life. There is the ability to image the tumor intraoperatively and thereby reducing the surgical excision rate. In addition, adjuvant therapy may be administrated faster after ablative treatment, in the absence of a wound requiring healing. Furthermore, ablative treatment can be done under local anesthesia and/or conscious sedation instead of general anesthesia and in daycare setting, which can reduce treatment cost [21,22]. In a recent meta-analysis of Van de Voort et al. the overall complete ablation rate of thermal ablation of tumors<2 cm was 86% in 1266 patients [20]. This suggest that 14% of the patients will need a re-ablation which is at the low end of the estimates for the re-excision rates of 11-30% after BCS [5-8]. An important challenge of the ablation procedure is to determine whether the ablation procedure of the tumor volume is complete. A well-established technique would be a post procedural MRI which can determine complete necrosis and residual disease. There is a strong correlation between postprocedural MRI and pathological outcomes [23-25]. Microwave ablation is already being used in liver, kidney and lung tumors at the UMCG.

Study objective

To assess whether minimally invasive nonsurgical microwave ablation (MWA) followed by postprocedural MRI scan can be an alternative treatment for breast surgery in early stage breast cancer: a non-inferiority study .

Is the quality of life, cosmetic outcome, fear of breast cancer recurrence, and costs in patient treated with MWA non-inferior compared to patients treated with breast surgery?

Study design

Clinical, consecutive, prospective feasibility study.

Intervention

All 15 patients will undergo ultrasound guided minimally invasive nonsurgical MWA under local anesthesia. The patient will undergo a MRI scan on the day of admission to the hospital for standard breast surgery.

Breast surgery (breast conserving surgery or mastectomy with a sentinel node procedure) as standard care and gold standard is performed in all patients

within a maximum of 35 days from diagnosis (conform guidelines). The results of the MWA have no influence on the surgical procedure.

For the assessment of the cosmetic outcome, the breast Q preprocedure will be used before the microwave ablation. For breast cancer recurrence fear, the Lerman Breast Cancer Worry scale will be applied and for overall QoL the EuroQol 5D5L and for cosmetic outcome the breast Q postprocedure. These three evaluation will be done 4 days and 2 weeks after the MWA and 4 days, 2 weeks and 2 months after surgery.

Study burden and risks

Micorwave ablation:
Complications of the ablation treatment were reported in 9.8% of all patients (123/1258) [22]. The most common complications were skin burns (3.5%) and pectoralis major muscle damage (1.1%). The change of pneumothorax was 0.2% [22]. In the meta-analysis of Mauri et al. the minor (local discomfort and grade-1 skin burns) and major (grade 2 or 3 skin burns and skin necrosis) complications pooled rate was 8% and 6%, respectively [21]. To avoid these complications, administration of saline between the tumor and skin/musculus pectoralis major will be applied to create an adequate buffer spacing to avoid any unwanted warmth effects of the microwave needle. In literature a margin of 2 mm between tumor and adjacent tissue was used to protect the adjacent tissue[26]. However to further decrease the risk for complications we use a hydrodissection for all patients regardless of the distance between tumor and skin/muscle.

MRI: Until now, no hazardous effects of MRI are documented. The burden for the patient is an extra MRI scan of 20 minutes. This MRI is scheduled on day that the patient is admitted to the hospital for the standard breast surgery.

Burden for the patient:
Questionnaires: one questionnaire, Breast Q preprocedure, should be filled in before the MWA. This will take 5 minutes.
After the MWA three questionnaires (Breast Q postprocedure, Lerman Breast Cancer Worry scale and EuroQol 5D5L) at 2 different time points (4 days and 2 weeks after MWA) should be filled in by the patient this will take 15 minutes (5 minutes per questionnaire) at each time point.
After the standard surgery the same three questionnaires (Breast Q, Lerman Breast Cancer Worry scale and EuroQol 5D5L) at 3 different time points (4 days, 2 weeks and 2 months) should be filled in by the patient this will take 15 minutes (5 minutes per questionnaire) at each time point.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patient age =/> 18 years old and a solid non-lobular invasive breast tumor with a size <2cm based upon ultrasound and MRI measurements without mammographic or MRI evidence of extensive disease (e.g. calcifications or non-mass enhancement). The patient has no involved lymph nodes on ultrasound and MRI scan.

Exclusion criteria

Patients with more than one breast tumor, (lymph node) metastases, breast implants or neoadjuvant chemotherapy. Also patients who are pregnant or are breastfeeding cannot participate in this study.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-10-2023
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Microwave abalation system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-01-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-04-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL81767.042.22