The Treatment of Breast Cancer with PercutaneousThermal Ablation: A phase 2 screening trial

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The overall study aim is to determine the efficacy rate of complete ablation for the most promising types of thermal ablation (RFA, MWA or CA) technique for patients with early stage breast cancer (cT1N0M0) without an extensive component of DCIS (

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

Summary

ID

NL-OMON49602

Source
ToetsingOnline

Brief title
THERMAC

Condition

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

Synonym
breast cancer, breast neoplasms

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Ziekenhuis

Source(s) of monetary or material Support: AngioCare,IceCure,Team Westland;Stichting Coolsingel;Stichting Havenziekenhuis;Stichting Bevordering Onderzoek Franciscus

Intervention

Keyword: Ablative techniques, Breast cancer, Minimal invasive, Patient reported outcomes

Outcome measures

Primary outcome

The proportion of patients in whom complete ablation was achieved by RFA, MWA or CA, based on the histopathology of the resection specimen determined with CK8/18 and H&E staining.

Secondary outcome

• Feasibility of each technique in an outpatient setting, in terms of serious adverse events (SAE), complications, treatment tolerability and system usability.

• Predictive value of MRI for complete ablation of the tumor

• Patient satisfaction, measured with numeric pain scales, visual analog scale and open questions.

• Cosmetic outcome measured with BCTOS-13, Breast-Q and BCCT.core

• Degree of immune response of the three techniques: local response measured in tissue, and peripheral response measured in blood samples.

Study description

Background summary

With 15,000 new patients per year, breast cancer is the most common type of cancer among women in the Netherlands. Almost half of the tumors are smaller than 2 cm. These patients have an excellent prognosis with current surgical

therapy (five year survival rate of 98-99%). However, these patients could presumably have less invasive treatment without surgery, which might improve health-related quality of life. Percutaneous thermal ablation has the potential to replace surgical treatment. The most promising methods of percutaneous thermal ablation are radiofrequency ablation (RFA), microwave ablation (MWA) and cryoablation (CA). Success rates of RFA, MWA and CA are 82-87%, 83-90% and 74-75%, respectively. Currently, RFA and CA are tested in large prospective studies. Preliminary data suggest comparable outcomes to breast conserving surgery (BCS) with complete ablation rates of 91% and local recurrence rates of 0-0.6% after treatment with RFA an CA.

The differences in success rates (complete ablation) between *follow-up studies* and *treat and resect studies* remain unexplained. Possible explanations are heterogeneity of study designs, learning curve of the physicians or the timing of the evaluation of the complete ablation.

Additionally, activation of the immune system is found after thermal ablation in mice studies and other types of cancer but is never investigated in patients with breast cancer (9-12). The immune response might explain the differences in local disease control, but could possibly also prevent micro metastases and local recurrences (12,13).

Complications occurred in about 10% of patients in previous studies, mainly thermal damage to the skin or pectoral muscle (±6%) (14). Major adverse events, i.e. pneumothorax (0,2%) occurred incidentally (14).
Thus, previous studies indicate that RFA, MWA and CA can be safe and effective, but the actual success rate remains ambiguous. Even as feasibility in an outpatient setting, immune response, patient satisfaction and follow-up imaging of these techniques (6,15-23).

Research direction
A phase 2 study with RFA, MWA and CA under comparable conditions will provide more insight in which of these techniques has the best potential for treating early stage breast cancer without jeopardizing compromising treatment effectiveness compared to standard of care (surgery).

Study objective

The overall study aim is to determine the efficacy rate of complete ablation for the most promising types of thermal ablation (RFA, MWA or CA) technique for patients with early stage breast cancer (cT1N0M0) without an extensive component of DCIS (<= 25% of the tumor), when these techniques are performed in a standardized study design and comparable patient population, to warrant a randomized phase III trial comparing thermal ablation with surgery.

Primary Objective
The primary objective is to investigate if thermal ablation (RFA, MWA and CA)

is an effective treatment, in terms of complete ablation rate, for patients with early stage breast cancer (cT1N0M0) without an extensive component of DCIS (<= 25% of the tumor) in an outpatient setting.

Study design

A randomized prospective phase II screenings trial (pick-the-winner).

Intervention

Ultrasound guided percutaneous RFA, MWA or CA will be performed 1-2 weeks after diagnosis. Surgical resection will take place 3 months after thermal ablation in all patients. Surgical procedure will be according to the Dutch guideline (Mammacarcinoom 2.0) and will not be influenced by type of thermal ablation.

Study burden and risks

The risk of this investigation is mainly related to the risks of treatment by thermoablation. These risks are reversible and include mainly thermal damage to the skin or chest muscle.

The burden of the patients consist mainly of the additional treatment, and the additional examinations such as: an MRI scan, blood samples and completing questionnaires. These investigations are combined with standard follow-up appointments where possible. For example, the thermal ablation itself is combined with the localization of the tumor, which is a standard procedure. Only one extra appointment will be scheduled to perform an MRI and to collect blood. During this visit there is also the opportunity for the patient to ask questions to the coordinating investigator or another authorized person by the principal investigator.

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

1. Woman
2. Pathologically confirmed primary invasive breast cancer, unilateral, unifocal
3. A clinical T1N0M0 tumor (<2cm on US and/or MRI), without distant metastases. The largest dimension measured will be used to determine eligibility.
4. Tumor should be visible on ultrasound.
5. Postmenopausal; no menstrual period for at least 12 months.
6. Component DCIS < 25% of the tumor on MRI, complete area including DCIS component should not exceed 2cm.
7. The patient must have sufficient command of the Dutch language to complete Dutch questionnaires
8. Written informed consent

Exclusion criteria

1. History of invasive breast cancer
2. Pregnant or nursing
3. BRCA 1 or 2 positive
4. Breast augmentation
5. Electrical devices and/or implants
6. Neoadjuvant chemotherapy
7. Triple negative tumors
8. Lobular carcinoma
9. Allergic to local anaesthetics
10. HER2-neu overexpression tumors

11. Bloom-Richardson-Elston (BRE) grade 3 tumors

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2021
Enrollment:	63
Type:	Actual

Medical products/devices used

Generic name:	Radiofrequency ablation;Microwave ablation;Cryoablation
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-11-2020
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

ID: 26534
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL72970.078.20