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

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Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26534

Source
Nationaal Trial Register

Brief title
THERMAC

Health condition

Breast Cancer

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: Team Westland, Stichting Bevordering Onderzoek Franciscus, Stichting Coolsingel, Stichting Vrienden van het Havenziekenhuis, Maurits en Anna de Kock Stichting

Intervention

Outcome measures

Primary outcome

The primary outcome is to estimate the success rate in terms of the proportion of complete ablation at pathologic evaluation of the surgical specimen.

Secondary outcome

Feasibility of the three thermal ablation techniques (RFA, MWA, CA) in an outpatient setting; Predictive value of MRI for complete ablation when the tumor is treated with thermal ablation (RFA, MWA, CA); Patient satisfaction after thermal ablation (RFA, MWA, CA); Adverse events, side effects and cosmetic outcome after thermal ablation (RFA, MWA, CA) with adequate follow-up using validated questionnaires; System usability of each thermal ablation technique (RFA, MWA, CA); The immune response and the degree of this potential immune response after thermal ablation (RFA, MWA, CA).

Study description

Background summary

Introduction Breast cancer is the most common type of cancer among women worldwide. Almost half of the tumors are ≤ 2cm. These patients have an excellent prognosis with current surgical therapy (5-year survival rate of 98-99%). Percutaneous thermal ablation has the potential to replace surgical treatment and improve the health-related quality of life of these patients. Especially RFA, MWA and cryoablation are promising techniques as an alternative to surgical resection without jeopardizing current treatment effectiveness or safety. Success rates of RFA, MWA and cryoablation are 82-87%, 83-90% and 74-75%, respectively. Due to great heterogeneity between studies and a large variation in complete ablation rates, a formal recommendation on the best technique for a phase 3 study is not possible based on current literature. Additionally, to little is known about patient satisfaction and cosmetic outcome, immune response after thermal ablation, follow-up imaging, long-term benefits and complications. Therefore, the objective of this study is to determine the efficacy rate in terms of complete ablation for the most promising techniques of thermal ablation (RFA, MWA or CA) for patients with early stage breast cancer to warrant a randomized phase III trial comparing thermal ablation with surgery. Methods This is an open-label randomized phase 2 screening trial. Postmenopausal women diagnosed with unilateral invasive cT1N0M0 breast cancer with a DCIS component ≤ 25% of the total tumor will be included. A total of 63 patients will be randomized to radiofrequency ablation (n = 21), microwave ablation (n = 21) or cryoablation (n = 21). To evaluate whether the tumor was completely ablated, surgical resection will be performed 3 months after thermal ablation. The primary endpoint is the percentage of tumours with complete ablation at pathologic evaluation with CK8/18 and H&E staining. Secondary endpoints are: feasibility in an outpatient setting, degree of immune response, adverse events, patient satisfaction, cosmetic outcome and the predictive value of MRI.

Study objective

We hypothesize that success rates in terms of complete ablation rate will be comparable across the techniques and that only minor complications will occur in ≤10% of all patients. We mainly expect differences in patient satisfaction because of differences in treatment time and temperature.

Study design

MRI before thermal ablation, 2 weeks after thermal ablation and before surgical resection Cosmetic outcome questionnaire (Breast-Q and BCTOS-13), before thermal ablation, before surgical resection, two weeks after surgical resection, one year after surgical resection, 4 years after surgical resection Cosmetic outcome photographs (BCCT.core), before thermal ablation, before surgical resection, two weeks after surgical resection, one year after surgical resection, 4 years after surgical resection Blood withdrawal, 2 weeks after thermal ablation, before surgical resection, and two weeks after surgical resection Thermal ablation procedure within 2 weeks after inclusion

Intervention

Cryoablation (CA), Radiofrequency ablation (RFA) and Microwave ablation (MWA)

Contacts

Public
Franciscus Gasthuis & Vlietland
Elles van de Voort

010 461 6161
Scientific
Franciscus Gasthuis & Vlietland
Elles van de Voort

010 461 6161

Eligibility criteria

Inclusion criteria

1. Woman 2. Age > 45 years and postmenopausal; no menstrual period for at least 12 months. 3. Pathologically confirmed primary invasive breast cancer, unilateral, unifocal 4. A

clinical T1N0M0 tumor (≤ 2cm on US and/or MRI), without distant metastases. The largest dimension measured will be used to determine eligibility. 5. Tumor should be visible on ultrasound. 6. Intraductal component ≤ 25% of the tumor on MRI, complete area including intraductal component should not exceed 2cm. 7. Sufficient knowledge of the Dutch language to complete the 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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2021
Enrollment:	63
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Deidentified individual clinical trial participant-level data, protocols and the statistical analysis plan will be available upon reasonable request at publication. These data will be available for researchers who provide a methodologically sound proposal to achieve the aims in the approved proposal. Proposals should be directed to info@stichtingbor.nl and to gain

access, data requestors will need a data access agreement.

Ethics review

Positive opinion
Date: 20-01-2021
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49602
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9205
CCMO	NL72970.078.20
OMON	NL-OMON49602

Study results

Summary results
N/A