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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26534

Bron
NTR

Verkorte titel
THERMAC

Aandoening

Breast Cancer

Ondersteuning

Primaire sponsor: Franciscus Gasthuis & Vlietland
Overige ondersteuning: Team Westland, Stichting Bevordering Onderzoek Franciscus, Stichting Coolsingel, Stichting Vrienden van het Havenziekenhuis, Maurits en Anna de Kock Stichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Franciscus Gasthuis & Vlietland
Elles van de Voort

010 461 6161

Wetenschappelijk

Franciscus Gasthuis & Vlietland
Elles van de Voort

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	63
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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.

Ethische beoordeling

Positief advies

Datum:	20-01-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49602
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A