The treatment of breast cancer with thermal ablation: a pilot study

Published: 31-10-2019
Last updated: 10-04-2024

The primary objective is to investigate if thermal ablation of breast tumors less than 2cm with < 25% DCIS is effective in terms of the number of tumors in which complete ablation is found on pathology result.

Ethical review	Not approved
Status	Will not start
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON48001

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 (beschikbaar stellen van generator),IceCure (beschikbaar stellen van generator),Stichting Coolsingel;Stichting

Havenziekenhuis;Team Westland

Intervention

Keyword: Ablation Techniques, breast neoplasms, Immunomodulation, Patient reported outcome measures

Outcome measures

Primary outcome

The primary endpoint in the pilot study is the percentage of tumours with

complete ablation on pathology result 2.5 months after TA.

Secondary outcome

Secondary endpoints are: feasibility of the technique, predictive value of MRI

for success of the treatment, the degree and type of immune response, learning

curve, system usability radiologist, patient satisfaction, patient reported

cosmetic outcome, observed cosmetic result (BCCT.core).

Study description

Background summary

Breast cancer is the most common type of cancer among women in the Netherlands. Each year, nearly 15.000 new patients are diagnosed with breast cancer. Almost half of these women have a tumour smaller than 2 cm. With standard breast conserving surgery (BCS) and adjuvant therapy, these women have an excellent prognosis and a five year survival rate of 98-99%. In these women treatment could presumably be less invasive and surgery could even be avoided, percutaneous thermal ablation (TA) could be the suitable technique for this. Overall, radiofrequency ablation (RFA), microwave ablation (MWA) and cryoablation seem to be the most promising thermal ablation techniques but among these the success rate varies from 50-100%. Preliminary results from cohort studies with RFA and cryoablation show local recurrence rates of 0-0.6%, comparable to the recurrence rate after BCS. Although all three techniques appear safe and effective, based on current literature, technique selection is not possible because of limited evidence and lack of knowledge regarding complete ablation rate when tested under comparable circumstances, the immune

response, patient satisfaction and follow up imaging.

Both immediate and late effects occur after TA and the area of definite cell death can expand up to months after ablation. In previous studies resection and pathology are mostly done 1-4 weeks after TA with a maximum of 2 months. The three techniques are never tested under the same conditions with determination of the complete ablation rate after more than two months.

An activation of the immune system after thermal ablation is scientifically proven in mice studies and other types of cancer. However, this immune response has never been investigated in patients with breast cancer, treated with thermal ablation. The initiated immune response can presumably prevent micro metastases and local recurrences but could also provide new insights and leads for immunotherapy.

Patient satisfaction and cosmetic outcome are in most studies briefly described but outcomes of validated questionnaires are currently lacking in literature.

A randomized pilot study with all three of the techniques under comparable conditions will provide more insight in which technique has the most potential for treating early stage breast cancer without jeopardizing treatment effectiveness compared to standard of care, i.e. surgery.

Study objective

The primary objective is to investigate if thermal ablation of breast tumors less than 2cm with < 25% DCIS is effective in terms of the number of tumors in which complete ablation is found on pathology result.

Study design

An open 3-arm randomized controlled pilot trial.

Intervention

Ultrasound guided percutaneous RFA, MWA or cryoablation will be performed 1-2 weeks after diagnosis. Surgical resection will take place about 3 months after diagnosis. The type of surgical resection will be based on the Dutch guideline and will not be influenced by the type of thermal ablation.will be based on the Dutch guideline and will not be influenced by the type of thermal ablation.

Study burden and risks

The burden of the patient is mostly based on the additional treatment (thermal ablation) and the blood samples. All interventions will be combined with regular follow-up visits with the physician. For example the procedure will be

combined with localisation of the tumor. This way the patient anesthetic is only once indicated. The possible benefit for the patient is the possible immune response that will occur and the tumor will in most of the time be treated within 1-2 weeks, although surgery is still necessary after this. Mainly it will be for a greater good, to minimize the burden of the patients in the future who will not need a surgery when this treatment is as effective as expected. This could optimize patient reported satisfaction, cosmetic outcome and experienced illness.

Contacts

Public
Franciscus Ziekenhuis

Kleiweg 500
Rotterdam 3045PM
NL
Scientific
Franciscus Ziekenhuis

Kleiweg 500
Rotterdam 3045PM
NL

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 unifocal primary invasive breast cancer, unilateral

3. A clinical T1 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. Aged 18 years or older
6. Component DCIS < 25% on MRI as a total of the tumor
7. Written informed consent

Exclusion criteria

1. History of invasive breast cancer
2. Pregnant or nursing
3. BRCA 1 or 2 positive (if known)
4. Breast augmentation
5. Electrical devices and/or implants
6. Neoadjuvant chemotherapy
7. Triple negative tumors, Her2neu overexpression, Elston/Nottingham grade 3, lobular carcinoma
8. Allergic to local anaesthetics

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	Radiofrequency ablation;Microwave ablation;Cyroablation

Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	31-10-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL70012.100.19