

minimal invasive treatment with radiofrequency ablation of breast carcinoma in elderly patients(>70 years) who are not or less fit for surgery

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This study investigates 3 different aspects of RFA treatment:1. Feasibility and safety of RFA treatment in elderly patients (> 70 years) with T1 breast carcinoma who are not or less fit for surgery.2. Efficacy of RFA treatment in elderly...

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

Summary

ID

NL-OMON31718

Source

ToetsingOnline

Brief title

radiofrequency ablation of breast carcinoma in elderly patients

Condition

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

Synonym

breastcancer, carcinoma of the breast

Research involving

Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: deelnemende afdelingen radiologie;chirurgie;pathologie en anaesthesie,Tyco Health Care

Intervention

Keyword: breast, carcinoma, elderly, rfa

Outcome measures

Primary outcome

- Feasibility of RFA
- Safety of RFA with registration of complications
- Efficacy RFA with evaluating possible local tumor recurrence in the breast by MRI and core needle biopsies
- Tumor recurrence (other organ than breast)
- Patients experience (see also appendix 3 en 4)

Secondary outcome

n.a.

Study description

Background summary

Breast carcinoma is a common disease. 30% of patients with breast carcinoma are older than 70 years. Most of these patients are treated with breast conservative surgery or ablation in combination with a sentinel-node procedure. Some patients are not or less fit for surgery. In these patients radiofrequency ablation can be applied to achieve local tumor control. RFA is a minimally invasive technique which uses needles which are placed in the tumor. An alternating current in the needle causes hyperthermia and destroys the tissue. This treatment can be performed under local epidural anesthesia.

Study objective

This study investigates 3 different aspects of RFA treatment:

1. Feasibility and safety of RFA treatment in elderly patients (> 70 years) with T1 breast carcinoma who are not or less fit for surgery.
2. Efficacy of RFA treatment in elderly patients (> 70 years)with T1 breast carcinoma who are not or less fit for surgery.
3. Patients experience study with: VAS pain scale and Quality of life *scores

Study design

observational study

Intervention

Radiofrequency ablation of T1 breast carcinoma (NOM0)

Study burden and risks

There is a relatively low risk of complications associated with the epidural anesthesia and the RFA treatment of the breast.

The mostly reported complications associated with the RFA treatment of the breast are pain and skin burns.

After RFA treatment several evaluation forms must be filled in(see also appendix 3 and 4 of the protocol.)

Therapy respons evaluation is performed by MRI (3 x with IV contrast) and several core needle biopsies after 6 and 12 months

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

- breastcarcinoma (biopsy proven) with positive estrogenreceptorstatus
- tumor:maximal diameter is 2 cm
- due to comorbidity the tumor is not treatable with surgery or patient does not want to receive surgical treatment
- tumor can be localised using ultrasound
- patient is older than 70 years
- informed consent

Exclusion criteria

- multiple carcinomas in the breast
- contra-indications for MR imaging
- hormone receptor negative tumors
- axillary lymph node metastasis
- metastasis in other organs

Study design

Design

Study type: Interventional

Masking:

Open (masking not used)

Control:

Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 01-12-2008
Enrollment: 10
Type: Actual

Ethics review

Approved WMO
Date: 14-08-2008
Application type: First submission
Review commission: METC Brabant (Tilburg)

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	NL20184.028.08