Breast cancer with low risk of recurrence:partial and accelerated radiation with three dimensional conformal radiotherapy (3DCRT) vs standard radiotherapy after conserving surgery (phase III study)

Published: 18-02-2010
Last updated: 06-05-2024

The study proposes to evaluate whether partial hypofractionated and accelerated irradiation of the sole surgical cavity, in patients suffering from breast cancer with low risk of local recurrence and who undergo conservative surgery, is not inferior...

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

Summary

ID

NL-OMON39567

Source
ToetsingOnline

Brief title
IRMA

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Modena University Hospital
Source(s) of monetary or material Support: KWF kankerbestrijding ondersteuning voor datamanagement

Intervention

Keyword: breast cancer, partial breast irradiation, radiotherapy

Outcome measures

Primary outcome

survival free of local ipsilateral recurrence as prime event

Secondary outcome

global survival, locoregional recurrence-free, distant recurrence-free, acute

and late toxicity (RTOG) and cosmetic result

Study description

Background summary

Irradiation of the breast after surgery of a tumor in the breast reduces the risk of recurrence in the breast (local recurrence). The standard irradiation consists of 25 to 33 fractions in 5 to 6.5 weeks. The whole breast is irradiated and in most cases a boost is given on the original tumor bed. Recently several research groups have suggested that irradiation of only the part of the breast, where the tumor was situated, could be sufficient for patients, who have a low risk for local recurrence.
The irradiated volume is much smaller, when partial breast irradiation is used instead of irradiation of the whole breast. The irradiation dose that is needed for partial irradiation can be administered in a shorter time: in this study 10 fractions will be administered, twice a day during five consecutive working days.

Study objective

The study proposes to evaluate whether partial hypofractionated and accelerated

irradiation of the sole surgical cavity, in patients suffering from breast cancer with low risk of local recurrence and who undergo conservative surgery, is not inferior to postoperative irradiation with conventional fractionation of the entire breast as regards local control (incidence of ipsilateral recurrences as prime event)

Study design

Multicenter phase III controlled randomized, unblinded study of non-inferiority.

Intervention

RADIOTHERAPY:
•Trial arm 38.5 Gy total in 10 fractions (3.85 Gy per fraction), twice a day with an interval of at least 6 hours between the two fractions, for five consecutive working days.
• Control arm 45 Gy/18 fractions, or 50 Gy/25 fractions, or 50,4 Gy/28 fractions , 1 fraction/day, 5 fractions/week +/- 10 - 16 Gy boost in 5-8 fractions, according to the institutional policy of each participating center.

Study burden and risks

Irradiation of the breast may lead to slight swelling of the breast and a skin reaction, both are reversibel.
Another risk may be that partial breast irradiaton increases the risk of recurrence of the disease outside the irradiated area compared to standard irradiation of the whole breast. That is why this study is only for patients with a low risk for recurrence of disease

Contacts

Public
Modena University Hospital

Via del Pozzo 71
Modena 41100
IT
Scientific
Modena University Hospital

Via del Pozzo 71
Modena 41100
IT

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Females with Histologically confirmed invasive breast cancer pT 1-2 (< 3 cm in diameter) pN0-N1 M0 .
- Unifocal disease (confirmed radiologically and histologically)
- Patients undergoing conservative breast surgery for neoplasms with a diameter < 3 cm and with biopsy of the sentinel lymph node or first instance axillary dissection.
- Breast resection margins histologically negative (>= 2 mm) at first intervention or after subsequent widening
- Radiological examination of the surgical specimen to assess the excision of the hidden lesions and/or the microcalcifications if present in the mammography carried out before surgery
- Positioning of 3-6 metallic clips, or in any case of an appropriate number to delineate the area of surgical exeresis (tumor bed)
- At least two weeks must have elapsed from the end of the chemotherapy if this is administered before the radiotherapy. In patients who do not receive chemotherapy, radiotherapy should start < 12 weeks after surgery.
- No chemotherapy must be carried out during or at least two weeks after completion of the radiotherapy
- Treatment with tamoxifen or aromatase inhibitors is allowed at the same time
- Age > =49
- performance status 0-2
- life expectancy at least 5 years
- written informed consent
- Non-hormonal contraception in patients of childbearing age
- Patients technically eligible for radiotherapy

Exclusion criteria

•In situ carcinoma (CLIS and DCIS)
•Non-epithelial breast neoplasms (sarcoma, lymphoma etc.)
•Micro/macrometastases in > 3 axillary lymph nodes; micro/macrometastases in the internal mammary and/or supraclavicular or subclavicular lymph nodes
•Multicentric carcinomas (lesions in different quadrants of the breast or in the same quadrant but separated by at least 4 cm) or clinically or radiologically suspected lesions in the ipsilateral breast, unless their tumoral nature was excluded through biopsy or fine needle sample.
•Palpable radiologically suspected ipsilateral or contralateral axillary, supraclavicular or infraclavicular, internal mammary nodes (unless their tumoral nature was excluded through biopsy or fine needle sample)
•Treatments for previous contralateral or ipsilateral breast cancers
•Paget's disease of the nipple
•Cutaneous involvement, independently of the tumor diameter
•Distant metastases
•Previous radiotherapy on the thoracic region
•Previous neoadjuvant chemotherapy
•Collagen diseases (systemic erythematosus lupus, scleroderma, dermatomiositis)
•Other pathological conditions that limit life expectancy to < 5 years
•Psychiatric diseases or disorders of other nature that prevent signing of informed consent for the treatment
•Other neoplasms in the last 5 years with the exception of skin tumors apart from melanoma and squamous intraepithelial lesions (SIL) of the uterine cervix
•Pregnancy and breast-feeding

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-10-2010

Enrollment:	420
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-08-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	06-09-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-11-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	04-12-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-08-2015
Application type:	Amendment
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	NL27657.028.09