Breast conserving therapy using Accelerated Partial Breast Irradiation (APBI) in elderly patients: a feasibility study

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Confirm favorable treatment results of international studies.Relate (loco regional) tumor control, side effects and (inter current) death to geriatric questionnaires/condition, co-morbidity and usage of medication.

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

Summary

ID

NL-OMON45136

Source
ToetsingOnline

Brief title
Breast conserving therapy using APBI in elderly patients

Condition

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

Synonym
Breast cancer, mammacarcinoom

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: subsidie is aangevraagd bij Pink Ribbon; Raden van Bestuur MC Haaglanden en Haga ziekenhuis hebben hun volledige medewerking toegezegd

Intervention

Keyword: APBI, Breast Cancer, Elderly

Outcome measures

Primary outcome

Confirm favorable tumor control and cosmetic outcome (< 5% grade >2 toxicity, <

5% local recurrence (5yr), > 90% good/excellent cosmetic result).

Secondary outcome

Gathering QOL, geriatric and other information for modeling patient outcome.

EORTC QOL C30/ breast module, ACE 27, registration multi-pharmacy, geriatric

screening questionnaire (incl. GFI ,G8 and VES 13). Also digital pictures will

be made after 3 and 5 years for objective cosmetic results.

Study description

Background summary

The treatment policy for elderly patients with early stage breast cancer is largely intuitive and is just partly based on evidence as these patients are often not included in phase II/III studies. As a consequence a relative large proportion is treated by breast ablation and sentinel node biopsy. Accelerated partial breast irradiation (APBI) either by intra-operative or external beam radiotherapy might be a good alternative for elderly patients offering less treatment burden in a shortened treatment time and a limited chance of recurrence. International studies using APBI claim equivalent tumor control and cosmetic results compared to conventional fractionated radiotherapy.
The elderly patient is a complex patient due to the age, the (geriatric) condition with frequent co-morbidity and usage of multiple medications. The

collection of information of these (geriatric) conditions in Dutch radiotherapy centers will give us a solid base to construct algorithms to predict patient outcome (tumor related, morbidity and intercurrent disease)

Study objective

Confirm favorable treatment results of international studies.
Relate (loco regional) tumor control, side effects and (inter current) death to geriatric questionnaires/condition, co-morbidity and usage of medication.

Study design

registration study applying treatment modalities with proven efficacy in international phase III studies in an elderly study population
Intervention: depending on the facilities of the centre either intra-operative radiotherapy at lumpectomy (21 Gy 90% isodose, *ELIOT procedure*) or postoperative external beam radiotherapy (3DCRT or IMRT, 10x3,4 Gy ICRU, 10 fractions in 2 weeks).

Study burden and risks

This registration study is aimed to confirm the favorable treatment results of randomized international studies so tumor control and cosmesis will be comparable with the conventional approach. As such the treatment will be less extensive than routinely applied (lumpectomy instead of ablation; less radiation treatments (1 intra-operative fraction or 10 external beam fractions in 2 weeks instead of 25 in 5 weeks). The extra burden will be the questionnaires and two digital pictures after 3 and 5 years to evaluate the cosmetic result. The EORTC C30 and breast module are basic and need 5-10 minutes of time (at start, at the end of treatment and every half year afterwards). The geriatric questionnaires (Groningen FI, G8 and VES 13) will take approx. 10 minutes to complete and will be offered at start, at the end of treatment and every half year. The co-morbidity and medication questionnaire will be offered at start (5-10 minutes) and checked for changes afterwards. A major effort will be done to convert the paper questionnaires to electronic questionnaires to facilitate the practical implementation of this study and future studies.

Contacts

Public
Haaglanden Medisch Centrum

Burgemeester Banninglaan 1

Leidschendam 2262 BA
NL
Scientific
Haaglanden Medisch Centrum

Burgemeester Banninglaan 1
Leidschendam 2262 BA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Histological confirmed breast cancer (DCIS and invasive) ductal subtypes
T1-2 smaller than 30mm as determined by ultrasound
N0 on palpation and ultrasound examination
Unicentric, Unifocal disease (radiological), multifocal when limited within 2 cm of the index lesion)
Age * 60
Any hormonal receptor status, hormonal therapy allowed following Dutch treatment guidelines
Technically eligible for lumpectomy or radiotherapy
No contra indications for lumpectomy and sentinal node procedure
Written informed consent
Willing to fill out the QOL, geriatric- and co morbidity questionaires - if applicable

Exclusion criteria

Patients not eligible / fit for lumpectomy and sentinal node procedure
pT2 (>30mm), pT3 and pT4
Positive surgical margins

Multi centricity; multifocal (> 2cm from the index lesion)
Extensive intraductal carcinoma; lympho-vascular invasion
Previous treatment of ipsilateral breast tumor (DCIS or invasive)
Paget disease of the nipple
Cutaneous involvement
Distant metastases; > pN1a
Previous radiotherapy on the ipsilateral breast
neo adjuvant chemotherapy for current malignancy
Collagen diseases (systematic erythematosus lupus, scleroderma, dermatomyositis)
Psychiatric diseases or other that prevents signing of informed consent
Other neoplasm's in the last 5 year with exception of skin tumors (excl melanoma) and intraepthelial lesions of the cervix uteri

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2011
Enrollment:	509
Type:	Actual

Ethics review

Approved WMO

Date:	01-08-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	11-05-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO Date:	26-04-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO Date:	15-10-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO Date:	19-12-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO Date:	19-05-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO Date:	15-03-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL32061.098.10