Image guided Pre-operative Accelerated partial Breast Irradiation (PAPBI): Defening radiotherapy sensivity.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25288

Source
Nationaal Trial Register

Brief title
PAPBI

Health condition

breast cancer, partial breast radiotherapy, pre-operative
borstkanker, partiele borst bestraling, pre-operatief

Sponsors and support

Primary sponsor: NKI-AVL
Plesmanlaan 121
1066 CX Amsterdam
Amsterdam, the Netherlands
Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

Tumor response after radiotherapy will histologically be evaluated. Local control will be evaluated during follow-up.

Cosmetic evaluation will take place including digital photographs which will be analyze using computer software as well as questionnaires for the patient and treating physician.

Secondary outcome

mRNA gene expression profiles, miRNA expression profiles and DNA copy number changes associated with response to radiotherapy defined as pathologic response assessed in the lumpectomy 6 weeks after radiotherapy will be identified. 60 Patients will be studied as a test set to identify predictive profiles.

Responders are defined as Complete Respons and >50% Partial Response 6 weeks after radiotherapy. It is estimated, based on literature, that 50% of the patients will be defined responders. 60 Patients will be studied as a test set to identify predictive profiles; 60 patients will be used as a validation set.

Study description

Background summary

Patients with early stage breast cancer are treated with a combination of surgery, radiotherapy and often with systemic therapy. Radiotherapy is part of breast conserving therapy and is known to reduce LR rates in all patients with 60-70% although the absolute benefit differs in different subgroups. So far, no patient groups can be defined in whom radiotherapy would not be necessary. It is estimated that in approximately half of the patients whole breast radiotherapy is not necessary, while in others the tumor might be resistant to radiotherapy. It is likely that tumor cells differ in their response to radiotherapy and thus influence the LR rate after BCT. If it would be possible to predict tumor response to radiotherapy, a more tailored treatment can be advised to individual patients (higher boost dose or primary mastectomy).

Study objective

Pre-operative accelerated partial breast radiotherapy will be superior compared to conventional radiotherapy for fibrosis and cosmetic outcome, and we think this new treatment will be superior to conventional post-operative whole breast radiotherapy which is used up till now.

Study design

1. 60 Patients will be studied as a test set to identify predictive profiles;

2. 60 patients will be used as a validation set.

Intervention

The additional procedures in this study are:

1. Biopsies before radiotherapy;

2. Cytology at day 2 and 12 of radiotherapy;

3. MRI before operation;

4. A Pet scan will be done twice;

5. Also, the sentinel procedure will take place before radiotherapy.

Contacts

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Eligibility criteria

Inclusion criteria

Patients ≥ 60 years of age with proven adenocarcinoma of the breast presenting with an unifocal lesion on mammogram and MRI (no diffuse microcalcifications), tumor size up till 3.0

cm.

Exclusion criteria

1. Age < 60 year;

2. Multifocal disease;

3. Lobulair carcinoom;

4. pN+.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2009
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-11-2010
Application type:	First submission

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
NTR-new	NL2515
NTR-old	NTR2633
Other	NKI : M08PBI
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A