The efficacy of radioguided occult lesion localisation (ROLL) versus wire guided lesion localisation (WGL) in breast conserving surgery for non palpable breast cancer: a randomised controlled trial

Published: 31-07-2007
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To evaluate the efficacy of ROLL versus WGL in breast conserving surgery for non-palpable breast cancer.

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

Summary

ID

NL-OMON35161

Source
ToetsingOnline

Brief title
ROLL trial

Condition

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

Synonym
breast cancer, breast carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: NWO is aangevraagd,Integraal Kankeroverleg Midden Nederland (IKMN)

Intervention

Keyword: breast conserving, non-palpable breast carcinoma, ROLL, WGL

Outcome measures

Primary outcome

1) The percentage of tumour-free margins (invasive and in situ) after the ROLL

vs. the WGL procedure (i.e. oncologic outcome).

2) The volume and maximum diameter of the lumpectomy of ROLL vs. WGL (i.e.

cosmetic outcome).

Secondary outcome

1) The cost-effectiveness of ROLL vs. WGL (i.e. operation time, radiological

localisation time, hospital stay and materials).

2) The degree of difficulty of the radiological and surgical procedure.

3) The degree of patient (dis)comfort of the radiological procedure ROLL vs.

WGL (number of procedures, pain, complications).

4) The success rate of the sentinel node procedure (visualisation and

localisation).

Study description

Background summary

Approximately 25% of breast cancers detected are non palpable. Accordingly, a localization technique is required to help the surgeon to find and remove the cancer. The current technique (wire guided localization) is difficult to perform and has a high rate of tumour positive margins in the resected specimen, requiring a second operation. A new approach in the localization and resection of non-palpable malignant breast lesions is *radioguided occult lesion localization* (ROLL).

Study objective

To evaluate the efficacy of ROLL versus WGL in breast conserving surgery for non-palpable breast cancer.

Study design

A multicenter, prospective randomized controlled trial. Eligible patients will be randomized for either radioguided occult lesion localization (ROLL) or wireguided localization (WGL).

Intervention

Wire Guided Localisation technique

Patients in the WGL group will undergo intratumoural injection of a nuclear radiotracer under stereotactic or ultrasound guidance, after injection a scintigraphic imaging is made to monitor the migration of the radiotracer. Afterwards a guide wire is inserted, again under stereotactic or ultrasound guidance23. The excision of the primary tumour is guided by the inserted wire and the sentinel node procedure is performed using preoperatively injected patent blue and a gamma probe.

ROLL technique

Patients in the ROLL group will undergo intratumoural injection of the radiotracer under stereotactic or ultrasound guidance. After scintigraphic imaging, the excision of the primary tumour and the sentinel node procedure are both guided by a gamma probe.
After localization the surgical excision is guided by the probe at its lowest sensitivity setting.

Study burden and risks

There is no extra burden pre-, per-, and post operative. The radiofarmacon is used standardly for the sentinel node procedure and is causing no damage to the patient.

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

Patients with a non palpable breast carcinoma who are eligible for a lumpectomy and sentinel node biopsy

Exclusion criteria

- Pregnant or lactating patients
- Patients with a multi focal carcinoma
- Patients with ductal carcinoma in situ (DCIS) or a lobular carcinoma in situ (LCIS) without invasive growth

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-11-2007
Enrollment:	316
Type:	Actual

Ethics review

Approved WMO Date:	31-07-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-04-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-08-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL15865.041.07