Ambulatory SNP under local anaesthesia in a subgroup of breast cancer patients - trial

Published: 23-10-2014
Last updated: 21-04-2024

Reduction of the mean number of operations under general anaesthesia per patient. Improvement of Quality of Life. Reduction of depressive symptoms and experienced anxiety.

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

Summary

ID

NL-OMON40766

Source
ToetsingOnline

Brief title
AMBULANT Study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breast cancer, local anaesthesia, sentinel node procedure

Outcome measures

Primary outcome

Primary outcome parameters are the number of operations under general anaesthesia per patient and the number of operations under local anaesthesia per patient.

Secondary outcome

Secondary outcome parameters are Quality of Life, experienced depressive symptoms and anxiety.

Study description

Background summary

In breast cancer patients, lymph node status is a key prognostic indicator. At present, axillary ultrasound with subsequent fine needle aspiration cytology of suspicious lymph nodes (US+FNAC) is widely used as a pre-operative staging method. When US+FNAC is negative, a sentinel node procedure (SNP) is performed during breast surgery. Nowadays, an axillary lymph node dissection (ALND) is generally performed if one of the abovementioned diagnostic entities reveals lymph node metastases. However, the extensive role of ALND in breast cancer patients with lymph node metastases may change or diminish in upcoming years due to emerging evidence that completion ALND (cALND) does not affect disease-free survival and overall survival in early BC patients with (sentinel) node-positive disease. Whether ALND is needed in these patients, should be based on (axillary) tumour load. Because of the fact that tumour load can only be reliably evaluated by SNP and not by US+FNAC, the role of SNP might become even more important in upcoming years. Ideally, the status of this sentinel lymph node is known prior to breast surgery, so a patient tailored treatment plan can be made and discussed with the patient before breast surgery. In this context, it would be very logical to perform a SNP under local anaesthesia (LA), prior to breast surgery. This might not only lead to significantly less two-step surgical procedures under general anaesthesia (GA), but might also lead to a reduction of depressive symptoms and anxiety and

improved quality of life (QoL) of BC patients, because BC patients are in particular risk for psychological distress in the first three months after diagnosis of BC. Knowing lymph node status and the complete treatment plan as soon as possible (by performing a SNP under LA), might reduce this psychological distress. To investigate which breast cancer patients would benefit most from SNP under LA, we recently analysed 1132 breast cancer patients retrospectively. Both prevalence of axillary lymph node metastases and prevalence of false negative results of US+FNAC were directly associated with age <60 years and with primary breast tumour size >20 mm. Hence, these breast cancer patients might benefit most from SNP under LA. In the present study, the value of SNP under LA in these BC patients (i.e. <60 years with a breast carcinoma >20 mm) will be analysed.

Study objective

Reduction of the mean number of operations under general anaesthesia per patient. Improvement of Quality of Life. Reduction of depressive symptoms and experienced anxiety.

Study design

Prospective single centre randomised controlled clinical trial.

Intervention

Sentinel Node Procedure under Local Anaesthesia (SNP under LA)

Study burden and risks

Risks that are associated with participation are minimal. Risks that are associated with the sentinel node procedure under local anaesthesia are the following:
- pain during the procedure. If the patient reports pain during the procedure, more local anaesthetic is injected.
- Lidocain is used as a local anaesthetic during the sentinel node procedure under local anaesthesia. Lidocain may cause (1-10% of patients) tingling in the anaesthetized area, dizziness and nausea. More serious side effects, such as drowsiness and unconsciousness are very rare. Allergic reactions to lidocain are very rare (0.01-0.1% of patients).

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

- Female
- Age 18-60 years
- Diagnosis of invasive breast cancer
- Breast carcinoma measures >20 mm ultrasonographically
- Pre-operative axillary ultrasound (+ fine needle aspiration cytology) is negative or inconclusive
- No evidence of distant metastases
- Signed informed consent

Exclusion criteria

- History of previous breast surgery in the affected breast
- History of previous axillary surgery in the ipsilateral axilla
- History of radiation therapy (affected breast of axilla)
- History of neo-adjuvant therapy (for the breast cancer)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	23-10-2014
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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
ClinicalTrials.gov	NCT02187718
CCMO	NL49489.094.14

Study results

Date completed:	01-07-2016
Actual enrolment:	12

Summary results
Trial is onging in other countries