Sentinel Node And Recurrent Breast cancer

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22722

Bron
NTR

Verkorte titel
SNARB

Aandoening

Recurrent breast cancer
Sentinel node biopsie

Recidief mammacarcinoom
Schildwachtklierprocedure

Ondersteuning

Primaire sponsor: The principal investigator of this study is mrs. A. Maaskant-Braat, resident surgery
Overige ondersteuning: This research is not sponsored;it is self-financed.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Registration of technical feasibility of lymphatic mapping and sentinel node biopsy in patients with locally recurrent breast cancer.
- Registration of success rate of lymphatic mapping and SNB in patients with locally recurrent breast cancer.
- Registration of validity of lymphatic mapping and sentinel node biopsy in patients with locally recurrent breast cancer.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Like in primary breast cancer, prognosis in recurrent breast cancer is correlated with regional lymph node status. Therefore, it seems sensible to perform lymphatic staging in case of an intact axillary lymph node basin, although this has not been described in guidelines yet. Due to surgery and radiotherapy lymph drainage pathways could be altered. These aberrant drainage pathways could be detected with lymphatic mapping and sentinel node biopsy leading to a more thorough staging and possible change in treatment strategy.

Objective:

To propose a regional staging protocol, lymphatic mapping and sentinel node biopsy, for patients with locally recurrent breast cancer in the absence of guidelines for regional staging procedures and to registrate data derived from this study.

Study design:

A prospective, multicenter, national registration study.

Study population:
At least 150 women above 18 years old with locally recurrent breast cancer after earlier BCT or modified radical mastectomy.

Main study parameters/endpoints:
Registration of technical feasibility and validity of lymphatic mapping and sentinel node

biopsy in patients with locally recurrent breast cancer as well as registration of lymphatic drainage pathways and sentinel lymph node status. Furthermore, the influence of this staging procedure on therapeutic decisions will be evaluated.

Doel van het onderzoek

Due to surgery and radiotherapy lymph drainage pathways in recurrent breast cancer could be altered. These aberrant drainage pathways could be detected with lymphatic mapping and sentinel node biopsy leading to a more thorough staging and possible change in treatment strategy.

Onderzoeksopzet

- Pre-operative inclusion

- Operation

- Post-operative registration: first post-operative consult

Onderzoeksproduct en/of interventie

Lymfatic Mapping and sentinel lymph node biopsie.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Women above 18 years old with locally recurrent breast cancer after earlier BCT or modified radical mastectomy.

2. Operable cytological /histological confirmed locally recurrent breast cancer.

3. Having obtained an informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Proven ipsi- or contralateral regional lymph node metastases (ultrasound and FNA).

2. Known to be allergic to “99mTc-colloidal albumin” or blue dye injection fluids.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2008
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-09-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1390
NTR-old	NTR1450
Ander register	NL 19199.060.07 : M07-1792
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A