Multicenter studie naar de klinische relevantie van één injectie per tumor voor de schildwachtklierprocedure bij patiënten met multiple borsttumoren

Gepubliceerd: 12-08-2014 Laatst bijgewerkt: 18-08-2022

AIM: Establish the clinical value of sentinel node biopsy in patients with multiple breast tumors. Investigate if an intratumoral tracer injection in the additional tumors results in visualization of extra sentinel nodes/extra lymphatic drainage...

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

Samenvatting

ID

NL-OMON24033

Bron
NTR

Verkorte titel
MULTISENT-II

Aandoening

breast cancer, multifocal breast cancer, sentinel lymph node

Ondersteuning

Primaire sponsor: NKI-AVL
Rijnland ziekenhuis Leiderdorp
Overige ondersteuning: NKI-AVL, Rijnland ziekenhuis Leiderdorp

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The aim of the study is to determine the clinical value of the sentinel node procedure in breast cancer patients with multiple tumors and to investigative whether an intratumoral injection of the radiopharmaceutical in each tumor will lead to identification of additional sentinel nodes and/or extra lymphatic drainage locations compared to an intratumoral injection of the radiopharmaceutical in the largest tumor only.

Toelichting onderzoek

Achtergrond van het onderzoek

Lymphoscintigraphy in breast cancer patients can determine the lymphatic drainage pattern and the location of the first draining lymph nodes, the sentinel nodes. Sentinel nodes are likely to be the first nodes to harbor tumor cells, which may alter the patients' management. The purpose of this study is to further establish the clinical value of lymphoscintigraphy and sentinel node biopsy in patients with multiple invasive tumors in one ore more quadrants of the breast. In a first evaluation of the M08ML study including 50 patients receiving separate tumor 99m Tc-nanocolloid injections a 64% additional lymphatic drainage was found after tracer administration in the smaller tumors of the breast.1 In only 5 patients the additionally detected sentinel nodes contained tumor; however, in these patients also the sentinel nodes draining from the largest tumor contained metastases. In two other patients isolated tumor cells were found only in the additional sentinel nodes. Based on the findings of this first evaluation, and following the recommendations of the reviewers of the manuscript, the investigators consider a follow-up to the study as necessary. In this modified follow-up study an additional number of patients will be evaluated in order to demonstrate, or exclude, the clinical relevance of the additional sentinel nodes. In order to simplify the protocol all tumors in the breast will be injected at the same time.

Doel van het onderzoek

AIM: Establish the clinical value of sentinel node biopsy in patients with multiple breast tumors. Investigate if an intratumoral tracer injection in the additional tumors results in visualization of extra sentinel nodes/extra lymphatic drainage basins in comparison to an intratumoral injection in the largest tumor (standard).

HYPOTHESIS: There is a difference in lymphatic drainage pattern (and thereby the number /location of the sentinel node(s)) between the largest tumor and the additional tumors.

Onderzoeksopzet

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Onderzoeksproduct en/of interventie

Patients who are scheduled for a sentinel node procedure will receive two injections with radioactive labelled nanocolloid. In the (most) medial tumor ICG-99mTc-nanocolloid will be administered, in the lateral tumor(s) the standard 99mTc-nanocolloid is injected. After both injections the normal procedure will be followed.

Contactpersonen

Publiek

H.S.A. Oldenburg
NKI-AVL, department of Surgery
Plesmanlaan 121
Amsterdam 1066 CX
The Netherlands
+31205122551

Wetenschappelijk

H.S.A. Oldenburg
NKI-AVL, department of Surgery
Plesmanlaan 121
Amsterdam 1066 CX
The Netherlands
+31205122551

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients presenting at one of the participating centers with two or three invasive tumors in one or more quadrants of the breast

2. The minimal distance between two different invasive foci must be two centimeters

3. The minimal diameter of an invasive focus (of one tumor) must be one centimeter

4. Patients are clinically staged with negative lymph nodes in the axilla.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. The maximum diameter of the tumor larger than five centimeters

2. Evidence of other breast-cancer related disease such as palpable or ultrasound detected lymph node metastases or distant metastases.

3. Exclusive presence of ductal carcinoma in situ (DCIS).

4. Incapacity or unwillingness of participant to give written informed consent

5. Patients with known allergy to patent blue;

6. Patients who are pregnant or nursing mothers

7. History of hypersensitivity reactions to products containing human serum albumin

8. History of iodine allergy

9. Hyperthyroid or thyroidal adenoma

10. Kidney insufficiency

Onderzoeksopzet

Opzet

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2014

Aantal proefpersonen:	58
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-08-2014
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	NL4569
NTR-old	NTR4737
Ander register	MULTISENT-II : M13MUL

Resultaten

Samenvatting resultaten
Brouwer et al., EJNMMI 2012