BOOG 2013-07: The value of completion axillary treatment in sentinel node positive breast cancer patients undergoing a mastectomy.

Gepubliceerd: 16-09-2015 Laatst bijgewerkt: 15-05-2024

Completion axillary treatment can be safely omitted in sentinel node positive breast cancer patients undergoing a mastectomy and results in a significantly lower axillary morbidity rate and an improved quality of life.

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

Samenvatting

ID

NL-OMON29048

Bron
Nationaal Trial Register

Aandoening

breast neoplasms; breast cancer; axillary lymph node dessction; mastectomy.

Ondersteuning

Primaire sponsor: Pink Ribbon, KWF, CZ
Overige ondersteuning: sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Regional recurrence rate after 5- and 10 years of follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

Clinically T1-2N0 (tumour < 5 cm) invasive breast cancer with a limited positive sentinel lymph node, undergoing mastectomy are randomized for no no completion axillary treatment (axillary lymph node dissection or radiotherapy of the axilla) or completion axillary treatment (standard care).

Doel van het onderzoek

Completion axillary treatment can be safely omitted in sentinel node positive breast cancer patients undergoing a mastectomy and results in a significantly lower axillary morbidity rate and an improved quality of life.

Onderzoeksopzet

5- and 10 years.

Onderzoeksproduct en/of interventie

Patients randomized for arm A will undergo completion axillary treatment. Completion axillary treatment can consist of an ALND or axillary radiotherapy in accordance to the Dutch breast cancer guideline. Axillary radiotherapy can be either level 1 and 2, or level 1, 2 and 3, including the supraclavicular nodes.

Randomization arm B (study arm): without completion axillary treatment.

Contactpersonen

Publiek

[default]
The Netherlands

Wetenschappelijk

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Female

2. Aged 18 years or older

3. Pathologically confirmed invasive unilateral breast carcinoma

4. A clinical T1-2 tumour (including multifocal or multicentric breast cancer)

5. Will be or is treated with mastectomy

6. Clinically node negative: no signs of axillary lymph node metastases at physical examination and preoperative axillary ultrasound (or negative cyto-/histopathology)

7. SLN procedure and its pathologic evaluation should be performed according to the Dutch breast cancer guideline

8. pN1mi(sn) or pN1(sn): at least one and a maximum of three axillary sentinel lymph nodes containing micro- and/or macrometastases.

9. Written informed consent

Furthermore, neoadjuvant systemic therapy and primary and secondary breast reconstructions are also allowed.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Clinically node positive pre-operative

2. Sentinel lymph nodes only containing isolated tumour cells (<0.2mm)

3. Solitary parasternal sentinel lymph node metastasis (pN1b)

4. Bilateral breast cancer

5. Irradical resection of primary tumour at time of randomization (applicable in case the

mastectomy is performed before randomization)

6. Evidence of metastatic disease

7. History of invasive breast cancer

8. Previous treatment of the axilla with surgery or radiotherapy (except surgery for hidradenitis suppurativa or for other superficially located skin lesions, such as naevi)

9. Pregnant or nursing

10. Other prior malignancies within the past 5 years (except successfully treated basal cell and squamous cell skin cancer, carcinoma in situ of the cervix or carcinoma in situ of the ipsilateral or contralateral breast) or unsuccessfully treated malignancies > 5 years before randomization

11. Unable or unwilling to give informed consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2015
Aantal proefpersonen:	878
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-09-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44960
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5238
NTR-old	NTR5495
CCMO	NL44110.031.13
OMON	NL-OMON44960

Resultaten

Samenvatting resultaten
1. L.M. van Roozendaal, J.H.W. de Wilt, T. Van Dalen, J.A. van der Hage, L.J.A. Strobbe, L.J. Boersma, S.C. Linn, M.B.I Lobbes, P.M.P. Poortmans, V.C.G Tjan-Heijnen, K.K.B.T. van de Vijver, J. de Vries, A.H. Westenberg, A.G.H. Kessels, M.L. Smidt. The value of completion axillary treatment in sentinel node positive breast cancer patients undergonig a mastectomy: a Dutch randomized controlled multicentre trial (BOOG 2013-07). BMC Cancer (2015) 15:610 DOI 10.1186/s12885-015-1613-2