Saving breast cancer patients from ineffective treatment.

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In vivo 31P MRS at ultra high field before and after the first cycle of neoadjuvant chemotherapy can predict the response to neoadjuvant chemotherapy in breast cancer patients.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28036

Bron
NTR

Verkorte titel
SPACE

Aandoening

breast cancer - borsht kanker
neoadjuvant chemotherapy - neoadjuvante chemotherapie
response to therapy - response op therapie
31P Magnetic Resonance Spectroscopy - fosfor Magnetische resonantie spectroscopie
MRI- MRI

Ondersteuning

Primaire sponsor: University Medical Centre Utrecht
Amsterdam Medical Centre
Overige ondersteuning: Alpe d'Huzes foundation
KWF

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study parameters are the signal ratios of ME/PDE or alternatively PME/Pi as obtained with 31P-MRS that should discriminate between responders and non-responders. Non responders show unchanged or even higher PME/PDE and PME/Pi ratios after the first cycle of chemotherapy whereas (partial) responders show a significant decrease in these ratios.

Toelichting onderzoek

Achtergrond van het onderzoek

Chemotherapy before surgery (neoadjuvant chemotherapy) is used in patients with aggressive breast cancer to shrink the tumor and to prevent the chance of distant metastases. Unfortunately, the effect of neoadjuvant chemotherapy can only be assessed in a late phase of the therapy. Therefore, in case of an ineffective therapy, patients already suffered from the side effects of chemotherapy without any benefit. Currently, no good non-invasive method capable of assessing the efficacy of chemotherapy before the surgery is available. Although studies using Magnetic Resonance Imaging (MRI) detected changes in vascularity and cell density, no threshold value was established that could predict response to chemotherapy early after the start of treatment. The reason for this could be that parameters such as vascularity and cell density do not reflect tumor metabolism, which may be a better indicator of tumor aggressiveness and will be influenced by chemotherapy in an earlier stage than that changes in vascularity or cell density present.
Preclinical studies indicate that the phospholipid membrane metabolism –responsible for cell membrane synthesis- is changed in cancer. We have developed a unique setup, consisting of a high field MRI scanner (7 Tesla) and dedicated receiver coils, capable of assessing this aberrant metabolism in a non-invasive way directly in the patients by using 31P-Magnetic Resonance Spectroscopy (31P-MRS).

Purpose: To determine by 31P MRS early on in the course of neo-adjuvant chemotherapy whether or not a breast cancer patient responds to the chemotherapy. This enables the identification of patients that benefit from neo-adjuvant chemotherapy and prevent patients that do not respond to neo-adjuvant chemotherapy from having ineffective chemotherapy

Doel van het onderzoek

In vivo 31P MRS at ultra high field before and after the first cycle of neoadjuvant chemotherapy can predict the response to neoadjuvant chemotherapy in breast cancer patients.

Onderzoeksopzet

MRS/MRI:
before first cycle of NAC, 2 weeks after first cycle of NAC.
Pathological response:
after 6 cycles of NAC at surgery.

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

University Medical Centre Utrecht, Room number Q 04 4311

J.P. Wijnen
Postbus 85500

Utrecht 3508 GA
The Netherlands
+31 (0)88 75 51353, +31 (0)30-2581098

Wetenschappelijk

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The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• age of 18 years or older

• female breast cancer patients (HER2 negative breast cancer, stage II or III)

• selected for neo-adjuvant chemotherapy

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• any prior surgery or radiotherapy to the ipsilateral breast
• Karnofsky score <= 70,

• Pregnant or lactating women

• Contra-indications to MRI scanning according to hospitals 7T MRI screening guideline of the UMCU.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	28-10-2014
Aantal proefpersonen:	126
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-11-2014
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	NL4709
NTR-old	NTR4980
Ander register	: dr. ir. Jannie Wijnen

Resultaten