Saving breast cancer patients from ineffective treatment.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28036

Source
NTR

Brief title
SPACE

Health condition

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

Sponsors and support

Primary sponsor: University Medical Centre Utrecht
Amsterdam Medical Centre
Source(s) of monetary or material Support: Alpe d'Huzes foundation
KWF

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary study parameters as measured with (DCE-MRI, DWI, CEST-MRI) of the tumor prior to chemotherapy and after the first cycle of chemotherapy:
- DCE-MRI: Ktrans and kep values;
- DWI: ADC values;
- CEST-MRI: magnetisation transfer ratio (MTR) values

Study description

Background summary

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

Study objective

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.

Study design

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

Intervention

none

Contacts

Public
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
Scientific
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

Eligibility criteria

Inclusion criteria

• age of 18 years or older

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

• selected for neo-adjuvant chemotherapy

Exclusion criteria

• 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-10-2014
Enrollment:	126
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-11-2014
Application type:	First submission

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
NTR-new	NL4709
NTR-old	NTR4980
Other	: dr. ir. Jannie Wijnen

Study results