The implementation of microarrays in cancer diagnosis (Microarray prognostics in breast cancer).

Gepubliceerd: 12-09-2005 Laatst bijgewerkt: 18-08-2022

Hypothesis: The implementation of microarray diagnostics is feasible in general practice in community hospitals.

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

Samenvatting

ID

NL-OMON26188

Bron
NTR

Verkorte titel
RASTER

Aandoening

Breast Cancer

Ondersteuning

Primaire sponsor: Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital, Amsterdam, The Netherlands
Overige ondersteuning: Dutch Health Care Insurance Board (CVZ), Diemen, The Netherlands;
Agendia BV, Amsterdam, The Netherlands.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The amount of succesfully performed diagnostic microarray tests as a proportion of the total number of accrued patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Recently we have identified a gene expression profile of 70 genes using microarray analysis, which was a more powerful prognostic factor for freedom of distant metastases than current clinicopathological features in node negative breast cancer patients up to 55 years of age (van ‘t Veer et al., Nature 2002; Van de Vijver et al., New Engl J Med 2002). To assess whether this 70-gene microarray test can be implemented in daily clinical practice we aimed to answer the following three questions: I. Is it feasible to collect fresh tumor samples in order to make this test available in pN0 breast cancer patients in community hospitals? II. What is the proportion of a ‘high’ versus a ‘low’ risk profile in node negative patients? III. What is the concordance between the 70-gene microarray risk profile and the metastasis risk as assessed with current Dutch guidelines based on clinicopathological factors (such as age, pT, tumor grade, hormonal receptor-status)?
A selected number of community hospitals, all different in their logistics and/or size are participating in this trial. Fresh tumor tissue samples of eligible patients will be collected within one hour after surgery and sent in RNAlater® to our hospital. A 70-gene microarray test will be performed in node negative patients with a representative tumor tissue sample; pN+ patients will be excluded. According to current Dutch guidelines (used for guiding adjuvant systemic treatment) for node negative patients, high risk is defined as age < 35 years, pT any size and grade 2-3 or pT > 1cm and grade 1, or age > 35 years, pT1-2 cm and grade 3, pT2-3cm and grade 2-3 or pT>3cm and any grade; all others are defined as low risk. After surgery, clinical decision making regarding adjuvant systemic treatment will initially be based on Dutch guidelines. After communication of the 70-gene microarray risk profile, changes in clinical decision making will be monitored. This study will show us whether the use of this kind of microarray diagnostics is feasible in daily clinical practice.

Doel van het onderzoek

Hypothesis: The implementation of microarray diagnostics is feasible in general practice in community hospitals.

Onderzoeksproduct en/of interventie

Diagnostic intervention with the 70-gene microarray profile giving a result of 'high' or 'low'

risk for distant metastasis and death.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Female patients with primary operable unifocal breast cancer without clinical signs of lymph node involvement or distant metastasis younger than 55 years of age.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A prior history of any malignancy with the exception of cervical dysplasia and basal cell carcinoma.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	22-01-2004
Aantal proefpersonen:	750
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2005
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	NL406
NTR-old	NTR446
Ander register	: N/A
ISRCTN	ISRCTN71917916

Resultaten

Samenvatting resultaten
N/A