

The implementation of microarrays in cancer diagnosis (microarray prognostics in breast cancer)

Submission date 27/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/09/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.microarrays.nl>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

The implementation of microarrays in cancer diagnosis (microarray prognostics in breast cancer)

Acronym

RASTER

Study objectives

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. To assess whether this 70-gene microarray test can be implemented in daily clinical practice we aimed to answer the following three questions:

1. Is it feasible to collect fresh tumour samples in order to make this test available in pN0 breast cancer patients in community hospitals?
2. What is the proportion of a high versus a low risk profile in node negative patients?
3. 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, tumour grade, hormonal receptor-status)?

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local ethics committee (Protocol Toetsingscommissie) on the 8th October 2003 (study ref: MO3ARR; letter ref: EV03-464).

Study design

Non-randomised, non-controlled, diagnostic multicentre clinical trial

Primary study design

Interventional

Secondary study design

Multi-centre

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Diagnostic intervention with the 70-gene microarray profile giving a result of 'high' or 'low' risk for distant metastasis and death.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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

Secondary outcome measures

1. To assess the proportion of a 'high' versus a 'low' risk profile in lymph node negative breast cancer patients
2. To assess 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)

Overall study start date

22/01/2004

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. Female patients
2. With primary operable unifocal breast cancer
3. Without clinical signs of lymph node involvement or distant metastasis
4. Younger than 55 years of age

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

750

Key exclusion criteria

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

Date of first enrolment

22/01/2004

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (NKI AVL)

Amsterdam

Netherlands

1066 CX

Sponsor information

Organisation

Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (NKI AVL) (The Netherlands)

Sponsor details

Plesmanlaan 121

Amsterdam

Netherlands

1066 CX

Sponsor type

Charity

Website

<http://www.nki.nl/>

ROR

<https://ror.org/03xqtf034>

Funder(s)

Funder type

Industry

Funder Name

Dutch Health Care Insurance Board (CVZ) (The Netherlands) - independent government organisation

Funder Name

Agendia B.V. (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2007		Yes	No
Results article	results	01/09/2011		Yes	No
Results article	10 year follow up	17/09/2022	27/09/2022	Yes	No