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

Submission date 27/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/02/2007	**Overall study status** Completed	
Last Edited 27/09/2022	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes