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Detection of circulating epithelial tumour cells (DETECT)

Submission date 17/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/05/2010	**Overall study status** Completed	
Last Edited 22/08/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.detetct-study.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DETECT 1

Study information

Scientific Title
A comparison of an antibody-based and an RT-PCR-based technique for the detection of circulating epithelial tumour cells: A multicentre, observational study

Acronym
DETECT

Study objectives
The aim of this prospective multi-centre trial was to compare the HER2 status of circulating tumour cells (CTCs) in 254 metastatic breast cancer patients at the time of first diagnosis or disease progression obtained by the antibody-based CellSearch® assay and the RT-PCR approach AdnaTest™ Breast Cancer and to assess the concordance rate between these two techniques.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local institutional review board of the University of Tuebingen, Germany approved on the 26th of September 2007 (ref: 2007/B01).

Study design
Prospective multicentre open label non-randomised observational trial

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Metastatic breast cancer

Interventions
Metastatic breast cancer patients were enrolled in this prospective open non-randomized and non-interventional study. Blood was drawn before the start of a new line of therapy.
1. Blood sampling mandatory (one or two times 50mL)
2. Bone marrow aspiration (not mandatory)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Rate of HER2 positive CTCs with each method

Secondary outcome measures
Concordance between the two methods in (HER2 positive) CTC detection

Overall study start date
01/12/2007

Completion date
01/04/2009

Eligibility

Key inclusion criteria
1. Epithelial invasive carcinoma of the breast with distant metastatic disease (M1)
2. Age ≤ 18 years
3. First diagnosis of metastatic disease or disease progression (before start of new treatment regimen)
4. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
254

Key exclusion criteria
Secondary primary malignancy (except in situ carcinoma of the cervix or adequately treated basal cell carcinoma of the skin)

Date of first enrolment
01/12/2007

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
Germany

Study participating centre
Dept of Gynaecology and Obstetrics
Tuebingen
Germany
72076

Sponsor information

Organisation
University of Tuebingen (Germany)

Sponsor details
c/o Prof. Dr. Tanja Fehm
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72076

Sponsor type
University/education

ROR
https://ror.org/03a1kwz48

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Institutional funding of participating centres (Germany)

Funder Name
Roche Pharma GmbH (Germany)

Funder Name
Adnagen GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	01/11/2010		Yes	No
Results article	results	11/07/2011		Yes	No