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Detection of circulating epithelial tumour cells (DETECT)

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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).

Primary study design
Observational

Study design
Prospective multicentre open label non-randomised observational trial

Study type(s)
Diagnostic

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(s)
Rate of HER2 positive CTCs with each method

Key secondary outcome(s)
Concordance between the two methods in (HER2 positive) CTC detection

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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)

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

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