

Detection of circulating epithelial tumour cells (DETECT)

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| Submission date 17/04/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 04/05/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 22/08/2012 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

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).

Study design

Prospective multicentre open label non-randomised observational trial

Primary study design

Observational

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 \leq 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 |