







Detection of circulating epithelial tumour cells (DETECT)

Submission date 17/04/2010	Recruitment status No longer recruiting	 Retrospectively registered
		 Protocol not yet added
Registration date 04/05/2010	Overall study status Completed	 SAP not yet added
		 Results added
Last Edited 22/08/2012	Condition category Cancer	 Raw data not yet added
		 Study completed

Plain English Summary

Not provided at time of registration

Study website

<http://www.detetct-study.de>

Contact information

Type(s)

Scientific

Contact name

Prof Tanja Fehm

Contact details

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72076

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

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 hypothesis

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

Condition

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

Overall study end date

01/04/2009

Eligibility**Participant 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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

254

Participant exclusion criteria

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

Recruitment start date

01/12/2007

Recruitment end date

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

Dept. of Gynaecology and Obstetrics

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Tuebingen

Germany

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