Detection of circulating epithelial tumour cells (DETECT)

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Tanja Fehm

Contact details

Dept of Gynaecology and Obstetrics Calwer Str 7 Tuebingen Germany 72076

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 D	ate added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2010		Yes	No
Results article	results	11/07/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025 1	1/11/2025	No	Yes
Study website	Study website	11/11/2025 1 ⁻	1/11/2025	No	Yes