PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Phase-IIb-Study to Evaluate the Effect of a Neoadjuvant Chemotherapy with Docetaxel, Epirubicine and Cyclphosphamide (TEC) in Patients with primary HER-2 neu Negative Mammacarcinoma

Trial Acronym

NeoTEC

URL of the trial

[---]*

Brief Summary in Lay Language

The treatment of the mammacarcinoma consists in this study normally on 6 chemotherapy cycles of the combination Docetaxel, Epirubicine and Cyclophosphamide (TEC-therapy). Followed by the surgery of the carcinoma, which takes place on day 28 after the last chemotherapy application, at the latest. An evaluation of the response of the treatment is performed after 2 and 4 cycles by use of palpation and mamma sonography. In case of complete remission, partial remission and no change the patient receives further two TEC cycles. In case of progress under therapy the surgery is immediately performed.

Brief Summary in Scientific Language

**Clinical studies have shown an equale effect in recurrence-free and total survival for neoadjuvant and adjuvant chemotherapies in patients with mammacarcinoma.
The primary systemic therapy allows an immediate evalution of the tumor response due to the treatment, this result is a important parameter in the prognosis of mammacarcinoma.
Pathologically proven complete remission are associated with a significant higher disease-free survival.
When giving a patient a primary systemic chemotherapie, the focus lies on the increase of the amount of breast preserving therapies and the toxicity profile of a chemotherapy and its tolerance, respectively.
The combination of Docetaxel, Epirubicine and Cyclophosphamide in this setting was so far little investigated.
The dose of TEC used in this study was chosen according to study results available so far especially from the adjuvant therapies.**

Organizational Data

- DRKS-ID: **DRKS00000162**
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DRKS-ID: **DRKS00000162**
Date of Registration in DRKS: **2009/07/20**

- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EK-AMG-MCF-25108-1 , Ethikkommission bei der Sächsischen Landesärztekammer**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1111-3764**
- EudraCT-No.
  (for studies acc. to Drug Law): **2008-003064-19**
- BfArM-No.: **4034658**

Health condition or Problem studied

- MedDRA: **10006187: Primary mamma carcinoma**
- ICD10: **C50 - Malignant neoplasm of breast**

Interventions/Observational Groups

- Arm 1: **neoadjuvant chemotherapy**
  6 cycles a:
  Docetaxel: 75 mg/m square
  Epirubicine: 75 mg/m square
  Cyclophosphamide 500 mg/m square

  and breast surgery

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Single arm study**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Uncontrolled/Single arm**

Purpose: **Other**

- Assignment: **Single (group)**
- Phase: **IIb**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Estimation of the complete remission rate of invasive tumor cells in the breast confirmed by histological examinations, at surgery.

Secondary Outcome

Tumor response according to clinical criteria determined by sonogrphy at surgery.
Tumor response according to pathological criteria determined by histology at surgery.
Rate of breast-conserving surgery
Toxicity associated with the therapy at each performed chemotherapy cycle.
Disease free survival until study end
Overall survival until study end

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/03/23**
- Target Sample Size: **150**
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Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2009/03/23**

Target Sample Size: **150**

Monocenter/Multicenter trial: **Multicenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Women with histologically verified mamma carcinoma (assessment of estrogen and progesterone receptors, grading, negative HER-2/neu status)
- All receptor-negative mamma carcinoma starting from cT1c, all receptor-positive mamma carcinoma starting from cT3, cT4 includes inflammatory mamma carcinoma
- In case of cT2 and receptor-positivity, N+ is required and can also be detected with sentinel node biopsy
- In case of cT1c and receptor-positivity, a positive lymph node must be verified with sentinel node biopsy (pNsn+)
- Clinically and with an imaging technology (sonography or mammography) measurable primary tumor
- Sufficient bone marrow reserve: number of neutrophils higher/equal 1,5 x 1000000000/L, number of thrombocytes higher/equal 100 x 1000000000/L, hemoglobin higher/equal 6,2 mmol/L
- Sufficient liver and renal function: bilirubin smaller/equal 1 x upper limit of quantification (ULQ), ASAT (SGOT) and ALAT (SGPT) smaller 1,5 x ULQ, alcalic phosphatase smaller 1,5 x ULQ, Creatinine smaller 1 x ULQ (if creatinine higher ULQ creatinine clearance must be higher 60 mL/minute)
- Age-appropriate cardiologically normal findings as documented by ECG and LVEF (echocardiographical) assessments before beginning the therapy
- ECOG-performance-status of 0-2
- Age greater/equal 18 years
- Written informed consent of the patient including compliance of the patient regarding the therapy and the follow-up must be available before enrolment and documented according to the local regulations.

Exclusion criteria

Pregnant or nursing women. Positive pregnancy test (urine or serum) within 7 days before registration
- Previous surgical, cytostatic or hormonal therapy (with exception of hormone substitution or contraception), no previous immune or radiation therapy
- Women with child bearing potency (menopause according to hormone status) without effective non-hormonal contraception (intra-uterine devices such as spirals, condoms in combination with additional contraceptic measures,

vasectomised partner) during the participation in the study and 6 months after the end of study therapy.
- Bilateral localisation of tumors
- Evidence of distant metastases after complete staging with chest X-ray, upper abdomen sonography, and/or CT and bone scintigraphy
- Pre-existing motor or sensor neurotoxicity > grade 2 (according to NCI criteria)
- Pre-existing cardiac disease not permitting the participation in this study (e.g. severe heart insufficiency or unstable angina pectoris, cardiac infarction within one year before study entry, uncontrolled hypertension, therapy resistant arrhythmia
- Significant neurological or psychiatric disease in the anamnesis (including psychotic disorders, dementia or seizures) compromising the understanding of the trial and consent to the trial.
- Drug abuse
- Active infection
- Florid ulcus, unstable diabetes mellitus
- Previously diagnosed tumor with exception of basalioma or in situ carcinoma of the cervix or other cancers having been treated curatively and having been followed by a disease-free interval of < 10 years.
- Chronic treatment with corticosteroids if not started > 6 months before study entry and at low doses (< 20 mg Methylprednisolone or equivalents)
- Clear contraindication for the application of corticosteroids
- Contraindication of the planned therapy:
- hypersensitivity to one of the trial drugs (Docetaxel, Cyclophosphamide and Epirubicine)
- extensive inflammatory condition of oral or gastrointestinal mucous membrane
- Lack of compliance
- Concomitant participation in other clinical trials

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/07/07**

Trial Publications, Results and other documents

- Paper **Senologie - Zeitschrift für Mammadiagnostik und -therapie 2012; 9 - A98. Erste Ergebnisse der Phase-IIb-Studie zur Erfassung der Effektivität einer neoadjuvanten Chemotherapie mit Docetaxel, Epirubicin und Cyclophosphamid (TEC) bei Patientinnen mit primärem HER-2 neu negativem Mammakarzinom (NeoTEC-Studie), D Langanke 1, U Wolfeneck 1, A Franke**

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*