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

Trial Description

Title

**Male breast cancer -
A prospective registry study
the University Women's Hospital Magdeburg in cooperation with the
GBG (German Breast Group)
the diagnosis and treatment of breast cancer man**

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**Breast cancer in male is very rare, but the observations in recent years showed an increase. For this particular case, there are no standardized guidelines for diagnosis and therapy. This study aims to assess the current register diagnostic and therapeutic approach in more detail.
In the study, tumor samples are collected for further studies too.
To learn more about the compatibility of applied treatments and the course of the disease out, all collected data will be centrally collected anonymously.
Data acquisition is multicentric in Germany and is to be at least 5 years.**

Brief Summary in Scientific Language

**The man's breast cancer is, with an estimated European prevalence of 1 per 100,000, a rare tumor disease represents. This is associated with a poor uniform data situation regarding the diagnosis and treatment. The clinical management of this disease is still based on the results generated by the research of breast cancer in women.
The purpose of this registry study is the detection of extensive data on history, diagnosis, pathology, therapy and course of the disease. These data will be the basis for the development of therapeutic concepts. Furthermore, the register study should be a prerequisite for the development of clinical trials, because only from the knowledge of "the current situation" can be meaningful clinical trials design.**

Organizational Data

- DRKS-ID: **DRKS00009536**
- Date of Registration in DRKS: **2015/10/30**

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- 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.: **114/09 , Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1175-5881**

Health condition or Problem studied

- ICD10: **C50.9 - Malignant neoplasm: Breast, unspecified**

Interventions/Observational Groups

- Arm 1: **The documentation of the data history, diagnosis, pathology, therapy and follow-up is made by the physician in charge of the participating institutions. The completed case report forms are sent to the study office at the University Women's Hospital.**

  The following data are collected:

  1. Patient data:
  - Signed agreement clarifying including for tumor removal.
  - Date of diagnosis, surgical data,
  - Data on radiation, chemotherapy, endocrine therapy, immunotherapy

  2.Tumor data: localization, histology, TNM, histology, grading, ER / PR receptor cerb-2 receptor, FISH, information resection margin, R classification, max. tumor diameter

  3. nodal status: total number of positive lymph nodes, the total number of lymph nodes examined,
  Total number of infected sentinel lymph nodes, the total number of examined sentinel nodes

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**

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Study Type Non-Interventional: **Other**

- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Supportive care**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

> Prospective recognition of the primary cases of breast cancer in men with the determination of recurrence-free survival

Secondary Outcome

> Determination of overall survival
> Stage and biological characteristics of breast cancer
> Validation of therapeutic modalities (medications, CHT, Op-type radiation)
> Sensitivity of diagnosis (clinical examination, ultrasound, mammography)
> Determining histopathological factors on tumor tissue

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsfrauenklinik Magdeburg, Magdeburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/09/09**
- Target Sample Size: **1000**
-

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Monocenter/Multicenter trial: **Multicenter trial**

- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

- Patient with histologically confirmed, primary breast cancer
- Written consent of the patient for data collection and for the histopathological provisions on tumor tissue.
- Inclusion of patients can only up to the beginning of chemotherapy
- If no chemotherapy must be given, inclusion within 6 months is possible after surgery

Exclusion criteria

no

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

Warburg - Melchior - Olearius Stiftung
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20095 Hamburg
Germany

Telephone: **040-32820**

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E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** 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.*