Trial Description

Title

Quality of Life During Neoadjuvant Chemotherapy of Breast Cancer

Trial Acronym

QOLNEO

URL of the trial

[---]*

Brief Summary in Lay Language

To explore the course of cancer- and treatment-related fatigue and health-related quality of life during chemotherapy preceding tumour surgery in breast cancer patients

Brief Summary in Scientific Language

Non-interventional study to explore the course of cancer- and treatment-related fatigue and health-related quality of life during neo-adjuvant chemotherapy of breast cancer patients

Organizational Data

- DRKS-ID: **DRKS00016761**
- Date of Registration in DRKS: **2019/05/06**
- 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.: **195/19 s , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **C50 - Malignant neoplasm of breast**

Interventions/Observational Groups

- Arm 1: **Female patients with malignant neoplasia of the breast are repeatedly asked over the course of neoadjuvant chemotherapy for their cancer-related fatigue and their health-related quality of life using the MFI-questionnaire "Multidimensional Fatigue Inventory" and the FACT-B questionnaire "Functional Assessment of Cancer Therapy - Breast Cancer", respectively.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

MFI questionnaire "Multidimensional Fatigue Inventory" at each chemotherapy cycle
FACT-B questionnaire "Functional Assessment of Cancer Therapy - Breast Cancer" at each chemotherapy cycle

Secondary Outcome

- SFQ questionaire "short fatigue questionnaire"
- Frequency of premature chemotherapy termination
- Frequency of delays or dose reductions of the chemotherapy
- Incidence and severity of adverse drug reactions of the neo-adjuvant chemotherapy by specific questions and including neutropenia

Countries of recruitment

- DE **Germany**
- CH **Switzerland**

Locations of Recruitment

- University Medical Center **Frauen- und Poliklinik der TU München, München**
- Medical Center **Klinik für Frauenheilkunde und Geburtshilfe, Esslingen am Neckar**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/06/12**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

1) Histologically confirmed UICC-stage I-III (without T0, Tis, T1mic) invasive adenocarcinoma of the breast
2) Planned neo-adjuvant chemotherapy according to the guidelines.
3) Age: 18 to 80 years
4) Gender: female
5) Performance status: ECOG 0-2
6) Legal competence
7) Voluntarily given written informed consent in advance for this observation.

Exclusion criteria

1) Pregnancy
2) Clinically significant concomitant condition critically influencing the ability of the patient to follow the requirements of the clinical observation.
3) Use of any investigational agent or participation in a clinical trial currently or during the last 4 weeks.

Addresses

- **Primary Sponsor**

  Gesellschaft für Klinische Forschung e.V.
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  Hardenbergstr. 20

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Sources of Monetary or Material Support

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

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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.*