Trial Description

Title
Safety, Efficacy and Patient Reported Outcomes of Advanced Breast Cancer Patients: Therapy Management With Nab-Paclitaxel in Daily Routine - SERAPHINA

Trial Acronym
SERAPHINA

URL of the trial
[---]*

Brief Summary in Lay Language

Despite treatment improvements in breast cancer, a large number of patients still progress to the metastatic stage. Metastatic breast cancer patients have an extremely unfavorable prognosis. Not only efficacy, but also quality of life are in the focus when planning a therapy or therapy sequence for metastatic breast cancer patients. Therapy options include anti-hormonal Therapy, antibody therapies, other targeted therapies and chemotherapies. One of the most effective chemotherapies in the adjuadjuvant and metastatic setting is paclitaxel. However drug handling and its side effects can compromise patients quality of life and can have an impact on the pharmacokinetics of the drug.

In metastatic breast cancer patients increasing therapy efficacy and reduction of side effect frequency are considered to be advancements of therapy. One of these advancements is the development of a cremophor free and albumin bound paclitaxel, nab-Paclitaxel (Abraxane), which is thought to have a better efficacy and reduced toxicity profile. Nab-Paclitaxel is approved for the treatment of metastatic breast cancer after a failure of first-line therapy and when antracyclines are not indicated.

The SERAPHINA study aims to investigate in the use of nab-Paclitaxel in daily routine and the frequency and perception of side effects.
As a non-interventional study, the SERAPHINA Study will assess the patient characteristics and describe the patient cohort, in which nab-Paclitaxel is given. This includes age distribution, molecular epidemiological characteristics and characteristics documented by the patients themselves.

Brief Summary in Scientific Language

Do you plan to share individual participant data with other researchers?

Description IPD sharing plan

Organizational Data

- **DRKS-ID:** DRKS00011389
- **Date of Registration in DRKS:** 2016/11/25
- **Date of Registration in Partner Registry or other Primary Registry:** 2015/12/09
- **Investigator Sponsored/Initiated Trial (IST/IIT):** yes
- **Ethics Approval/Approval of the Ethics Committee:** [--]*
- **(leading) Ethics Committee Nr.:** [--]*

Secondary IDs

- **Primary Registry-ID:** NCT02642406 (ClinicalTrials.gov)
- **Sponsor-ID:** SEN2015-01 (University Hospital Tuebingen)

Health condition or Problem studied

- **Free text:** Metastatic Breast Cancer
- **ICD10:** C50 - Malignant neoplasm of breast

Interventions/Observational Groups
Characteristics

- Study Type: Non-interventional
- Study Type Non-Interventional: Observational study
- Allocation: [---]*
- Blinding: [---]*
- Who is blinded: [---]*
- Control: [---]*
- Purpose: [---]*
- Assignment: [---]*
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

- Epidemiological assessment of progression free survival (PFS) under real life conditions.; time frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first; PFS defined as the time to the first progression or death after therapy start of nab-Paclitaxel.

Secondary Outcome

- Assessment of overall survival (OS); time frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first; OS (overall survival) is defined as the time to death from therapy start of nab-Paclitaxel. Reason for death is taken into consideration as well (BBCS, breast cancer specific survival).
- Influence of age on the prognosis and quality of life.; time frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first; Influence of age on the prognosis will be assessed with the standardized questionnaire FACT-B.
- Incidence of adverse events, serious adverse events will be reported.; time frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first; NCI Common Toxicity Criteria Version 4.03
- Quality of life Quality of life (FACTB, Version 4); time frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first; Patient reported (PRO) quality of life is assessed with the standardized questionnaire FACT-B, Version 4. specific questions,
- Quality of life (FACTB-TAXANE, Version 4); time frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first; Patient reported (PRO) quality of life is assessed with the standardized questionnaire FACT-B-Taxane, Version 4.
- Quality of life (NCCN-Distress-Thermometer); time frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first; Patient reported (PRO) quality of life is assessed with the standardized
questionnaire NCCN-Distress-Thermometer.
- Quality of life ("Special questions").; time frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first; Patient reported (PRO) quality of life is assessed with the questionnaire "Special questions".

Countries of recruitment

- DE Germany

Locations of Recruitment

- Aalen Brustzentrum, Aalen
- Universitätsklinikum Freiburg, Freiburg
- NCT Heidelberg, Heidelberg
- Frauenklinik des Städtischen Klinikums, Karlsruhe
- St. Vicentius Kliniken gAG, Karlsruhe
- Ortenau Klinikum Lahr-Ettenheim, Lahr
- Praxisklinik am Rosengarten, Mannheim
- Universitätsmedizin Mannheim, Mannheim
- Paracelsus Krankenhaus Ruit, Ruit
- Schwerpunktpraxis für Hämatologie und Internistische Onkologie, Gastroenterologie, Singen
- Brustzentrum, Stuttgart
- Universitätsfrauenklinik Tübingen, Tübingen
- GRN-Klinik Weinheim Abteilung für Gynäkologie und Geburtshilfe, Weinheim
- Klinikum für Frauenheilkunde und Geburtshilfe Esslingen, Esslingen
- MVZ Amberg, Amberg
- phase drei Hämato-Onkologischer Studienkreis am Klinikum Aschaffenburg, Aschaffenburg
- Klinikum Augsburg Frauenklinik, Augsburg
- Rottal-Inn-Kliniken GmbH, Eggenfelden
- Universitätsfrauenklinik Erlangen, Erlangen
- MOPS Elisenhof MOP-Studiengesellschaft, München
- Klinikum der Universität München (LMU), München
- Praxisgemeinschaft - Frauenärzte am Stadtpark, Nürnberg
- Caritas-Krankenhaus St. Josef, Regensburg
MVZ Weiden GmbH, Weiden
Praxis Dr. med. Uwe G. Pöhls und Kollegen Fachärzte für Frauenheilkunde und Geburtshilfe, Würzburg
Onkologische Gemeinschaftspraxis, Würzburg
Akad. Lehrkrankenhaus der Charité, Ludwigsfelde
Ruppiner Kliniken GmbH, Neuruppin
g.SUND Gynäkologie Kompetenzzentrum, Stralsund
Brustzentrum am Elisabeth-KH Leipzig, Leipzig
Klinikum Darmstadt, Darmstadt
Zentrum für Hämatologie und Onkologie Bethanien, Frankfurt
Agaplesion Markus Krankenhaus, Frankfurt
MVZ Onkologische Kooperation Harz, Goslar
Praxis Ammon/Meyer, Göttingen
Frauenklinik Wetzlar, Wetzlar
Niels-Stensen-Kliniken, Georgsmarienhütte
Gynäkologisch-Onkologische Praxis am Pelikanplatz, Hannover
Klinik f. Frauenheilkunde u. Geburtshilfe, Hannover
Frauenarzt Bewer und Sternberg Gynäkologie, Hannover
Gemeinschaftspraxis f. Hämatologie u. Onkologie, Westerstede
Facharztklinik am Schloß, Wolfenbüttel
Evangelisches Krankenhaus Bethesda Mönchengladbach GmbH, Mönchengladbach
MarienHospital Onkologische Praxis, Bonn
Marienhospital Bottrop gGmbH, Bottrop
Universitätsfrauenklinik Düsseldorf, Düsseldorf
Universitätsklinikum Essen, Essen
PIOH Praxis Internistischer Onkologie und Hämatologie, Frechen
Helios Klinikum Krefeld, Krefeld
Gemeinschaftspraxis f. Onkologie und Hämatologie, Köln
Kliniken der Stadt Köln g.GmbH, Köln
Johannes Wesling Klinikum Minden, Minden
Marienkrankenhaus/Brustzentrum, Schwerte
Recruitment

- Planned/Actual: [---]*
- (Anticipated or Actual) Date of First Enrollment: 2015/12/31
- Target Sample Size: 1200
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National

Inclusion Criteria

- Gender: Female
- Minimum Age: 18 Years
- Maximum Age: 99 Years

Additional Inclusion Criteria

- Patients with metastatic breast cancer in which a therapy with nab-paclitaxel was indicated by the treating physician
- Treatment of nab-Paclitaxel must either have not been started yet, or first application of nab-Paclitaxel was not prior to 21 days before study entry

- Female patients, age ≥18 years

- Invasive breast cancer (irrespective of status of BC, e.g. TNM, receptor status etc.)

- Metastatic or locally advanced, inoperable disease proven by clinical measures (i.e. standard imaging)

- Patients scheduled for nab-Paclitaxel treatment in daily routine before screening

- Patients, who are able and willing to sign the informed consent form

Exclusion criteria

- Patient is currently enrolled, or will enroll in an interventional clinical study in which investigational therapeutic procedures are performed or investigational therapies are administered while participating in this study

Addresses

- **Primary Sponsor**
  
  **University Hospital Tuebingen**
  
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  URL: [---]*

- **Contact for Scientific Queries**
  
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**Contact for Public Queries**

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**Sources of Monetary or Material Support**

[---]*

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

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

**Status**

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

**Trial Publications, Results and other documents**

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The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: [---]*
- Last processed date by ClinicalTrials.gov: 2016/11/23
* 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.