Therapy Management With Nab-Paclitaxel in Daily Routine (SERAPHINA)

This study is currently recruiting participants. (see Contacts and Locations)

Verified December 2015 by University Hospital Tuebingen

Sponsor:
University Hospital Tuebingen

Information provided by (Responsible Party):
University Hospital Tuebingen

ClinicalTrials.gov Identifier:
NCT02642406

First received: December 9, 2015
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History of Changes

Purpose

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.

Condition	Intervention
Metastatic Breast Cancer	Procedure: Blood sampling

Study Type: Observational
Study Design: Observational Model: Case-Only
Time Perspective: Prospective

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

Resource links provided by NLM:

Genetics Home Reference related topics: breast cancer

MedlinePlus related topics: Breast Cancer

Drug Information available for: Paclitaxel

U.S. FDA Resources

Further study details as provided by University Hospital Tuebingen:

Primary Outcome Measures:

- 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] [Designated as safety issue: No]

  PFS defined as the time to the first progression or death after therapy start of nab-Paclitaxel.

Secondary Outcome Measures:

- 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] [Designated as safety issue: No]

  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] [Designated as safety issue: No]

  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] [Designated as safety issue: No]

  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] [Designated as safety issue: No]

  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] [Designated as safety issue: No]

  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] [Designated as safety issue: No]

  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] [Designated as safety issue: No]

  Patient reported (PRO) quality of life is assessed with the questionnaire "Special questions".

Other Outcome Measures:

- Influence of breast cancer patient characteristics on prognosis. [Time Frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first] [Designated as safety issue: No]

  The patient group is described by patient and tumor characteristics, molecular epidemiological characteristics and a series of questionnaires assessing health and socio-economic status and geriatric assessment status. These parameters that describe the patient cohort will be analyzed with regard to their influence on prognosis, adverse event frequencies, quality of life and therapy decision making.

- Influence of breast cancer patient characteristics on adverse event frequencies. [Time Frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first] [Designated as safety issue: No]

  The patient group is described by patient and tumor characteristics, molecular epidemiological characteristics and a series of questionnaires assessing health and socio-economic status and geriatric assessment status. These parameters that describe the patient cohort will be analyzed with regard to their influence on prognosis, adverse event frequencies, quality of life and therapy decision making.

- Influence of breast cancer patient characteristics on quality of life. [Time Frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first] [Designated as safety issue: No]

  The patient group is described by patient and tumor characteristics, molecular epidemiological characteristics and a series of questionnaires assessing health and socio-economic status and geriatric assessment status. These parameters that describe the patient cohort will be analyzed with regard to their influence on prognosis, adverse event frequencies, quality of life and therapy decision making.

- Influence of breast cancer patient characteristics on therapy decision making. [Time Frame: A patient remains in the study for a maximum of 36 months or until death, whatever occurs first] [Designated as safety issue: No]

  The patient group is described by patient and tumor characteristics, molecular epidemiological characteristics and a series of questionnaires assessing health and socio-economic status and geriatric assessment status. These parameters that describe the patient cohort will be analyzed with regard to their influence on prognosis, adverse event frequencies, quality of life and therapy decision making.

Biospecimen Retention: Samples With DNA
Blood samples

Estimated Enrollment:	1200
Study Start Date:	December 2015
Estimated Primary Completion Date:	December 2018 (Final data collection date for primary outcome measure)

Intervention Details:

Procedure: Blood sampling

A blood sample will be taken during a routine blood draw before the application of any nab-Paclitaxel.

Eligibility

Ages Eligible for Study:	18 Years to 99 Years (Adult, Senior)
Genders Eligible for Study:	Female
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

1200 patients with locally advanced/metastatic breast cancer for who is curruently or will be treated with nab-Paclitaxel according to the approval as stated in the Summary of Product Characteristics.

Criteria

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

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02642406

Contacts

Contact: Erik Belleville, PHD +49 931 359200 ext 36 belleville@clin-sol.com

Locations

Germany

Universitätsfrauenklinik Tübingen **Recruiting**
Tübingen, Baden-Württemberg, Germany, 72076

Universitätsfrauenklinik Erlangen **Recruiting**
Erlangen, Bayern, Germany, 91012

Sponsors and Collaborators

University Hospital Tuebingen

Investigators

Principal Investigator:	Peter Fasching, Prof. Dr.	Frauenklinik des Universitätsfrauenklinikums Erlangen
Principal Investigator:	Hans Joachim Lück, Prof. Dr.	Gynäkologisch-Onkologische Schwerpunktpraxis am Pelikanplatz
Study Director:	Diethelm Wallwiener, Prof. Dr.	Universitätsklinikum Tübingen Universitäts-Frauenklinik
Study Director:	Sara Brucker, Prof. Dr.	Universitätsklinikum Tübingen Universitäts-Frauenklinik

More Information

Responsible Party:	University Hospital Tuebingen
ClinicalTrials.gov Identifier:	NCT02642406 History of Changes
Other Study ID Numbers:	SEN2015-01
Study First Received:	December 9, 2015
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Health Authority:	Germany: Federal Institute for Drugs and Medical Devices

Additional relevant MeSH terms:

Breast Neoplasms
Neoplasms by Site
Neoplasms
Breast Diseases
Skin Diseases

Antineoplastic Agents, Phytogenic
Antineoplastic Agents
Tubulin Modulators
Antimitotic Agents

Paclitaxel	Mitosis Modulators
Albumin-Bound Paclitaxel	Molecular Mechanisms of Pharmacological Action

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