Trial Description

Title

Non-interventional study about safety and efficacy of chemo-therapy with Paclitaxel Stragen(R) / Eurotaxel(R) (new name of the prescription) as mono or combined therapy for routine treatment of ovarial or breast cancer with special consideration of age and BMI starting position.

Trial Acronym

ET-001

URL of the trial

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Brief Summary in Lay Language

It is the aim of this non-interventional study to collect and analyze data about the efficacy and safety of a mono or combined therapy with Paclitaxel Stragen(R) / Eurotaxel(R) (new name of the prescription) for the treatment of ovarial or breast cancer with special consideration of age and BMI starting position. For this purpose the present analysis shall document the application of the taxane Paclitaxel Stragen(R) / Eurotaxel(R) as part of the routine diagnostic and therapy of this disease. The analysis of the data shall investigate if the age has an influence on the choice of the therapy regime or if the age has an influence on the therapy outcome. Likewise it shall be tried to ascertain that the BMI starting position has an influence on the outcome of the therapy of the different treatment groups. The assessment of the safety occurs by means of the NCI CTC check list version 4.0 for the evaluation of objective adverse reactions. The assessment of the efficacy occurs by means of the objective responder rate.

Brief Summary in Scientific Language

It is the aim of this non-interventional study to collect and analyze data about the efficacy and safety of a mono or combined therapy with Paclitaxel Stragen(R) / Eurotaxel(R) (new name of the prescription) for the treatment of ovarial or breast cancer with special consideration of age and BMI starting position.
Target parameters:
Progression Free Survival (PFS);
Overall Survival (OS);
Influence of age (≤ 65 years versus > 65 years) on therapy, PFS and OS;
Influence of BMI (< 19 kg/m² versus 19 - 30 kg/m² versus > 30 kg/m²) on therapy, PFS and OS;
Safety by means of CTCAE criteria.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00000781**
- Date of Registration in DRKS: **2011/04/11**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **011-1238 , Freiburger Ethik-Kommission International**

Secondary IDs

Health condition or Problem studied

- Free text: **Breast cancer, ovarial cancer**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>Observation group: Patients receive chemotherapy with Paclitaxel Stragen(R) / Eurotaxel(R) (new name of the prescription) according to physician's prescription. Parameters of differentiation are:
  Age (≤ 65 years versus > 65 years) and
  BMI (< 19 kg/m² versus 19 - 30 kg/m² versus > 30 kg/m²).

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Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**

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Study Type Non-Interventional: **Observational study**

Allocation: **Non-randomized controlled trial**

Blinding: **Open (masking not used)**

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

Control: **Active control**

Purpose: **Treatment**

- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

**Primary Outcome is progression free survival (PFS) measured after 3 and 9 months by means of the tumor response (complete remission, partial remission, abjictive stabilisation, objective progression).
Overall Survival (OS) is measured after 9 months or by the occurence of a corresponding SAE.**

Secondary Outcome

Influence of age (<= 65 years versus > 65 years) on therapy, PFS and OS. Influence of BMI (< 19 kg/ m² versus 19 - 30 kg / m² versus > 30 kg / m²) on therapy, PFS and OS. The measurements of age, height and weight are performed at therapy start, after 3 and after 9 months. Statistical tests are performed to secure a significant difference between the subgroups. Safety is measured by means of NCI CTCAE citeria by the investigator after 3 and 9 months.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/06/01**

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- Target Sample Size: **1500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Histologically secured ovarial or breast cancer.
Signed patient informed consent form.

Exclusion criteria

Pregnancy.
Other malign diseases in the past 5 years.
Lack of compliance.

Addresses

- **Primary Sponsor**

Lapharm GmbH
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83022 Rosenheim
Germany

Telephone: **08031 / 234550**
Fax: **08031 / 2345510**
E-mail: **r.heffinger at lapharm.de**
URL: **www.lapharm.de**

- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

Lapharm GmbH
Wittelsbacherstr. 9
83022 Rosenheim
Germany

Telephone: **[---]***
Fax: **[---]***
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.*