Trial Description

Title

Non-interventional study to evaluate neurotoxicity under therapy with Docetaxel Omnicare for patients with various tumor entities

Trial Acronym

NORDIC

URL of the trial

[---]*

Brief Summary in Lay Language

The study evaluates (by means of a patient questionnaire) neurological symptoms of patients with various cancer types who receive a therapy with Docetaxel Omnicare®

Brief Summary in Scientific Language

The study evaluates neurotoxicity under therapy with Docetaxel Omnicare® for patients with various tumor entities

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00008183**
- Date of Registration in DRKS: **2015/04/28**
- 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.: **2015091 , Ethikkommission der Ärztekammer Nordrhein**

Secondary IDs

Health condition or Problem studied

- ICD10: **C50 - Malignant neoplasm of breast**
- ICD10: **C34 - Malignant neoplasm of bronchus and lung**
- ICD10: **C61 - Malignant neoplasm of prostate**
- ICD10: **C44 - Other malignant neoplasms of skin**
- ICD10: **C16 - Malignant neoplasm of stomach**

Interventions/Observational Groups

- Arm 1: **Patients treated with Docetaxel Omnicare are asked to complete a questionnaire every 3 months under therapy and every 6 months after end of treatment. The questionnaire contains questions regarding the effect of treatment on daily life activities and general health condition of the patients.**

Characteristics

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

Primary Outcome

Evaluation of grade and duration of neurotoxicity for patients (every 3 months under therapy and every 6 months after end of treatment) under therapy with Docetaxel Omnicare by means of a patient questionnaire (FACT-GOG-Ntx)

Secondary Outcome

• Evaluation of neurotoxicity by the investigator by means of CTCAE criteria (version 4.0)
• Evaluation of adverse drug reactions of Docetaxel Omnicare®

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Neuss**
- Doctor's Practice **Leipzig**
- Doctor's Practice **Krefeld**
- Doctor's Practice **Celle**
- Doctor's Practice **Aachen**
- Doctor's Practice **Dortmund**
- Doctor's Practice **Köln**
- Doctor's Practice **Halle Saale**
- Doctor's Practice **Ansbach**
- Doctor's Practice **Berlin**
- Doctor's Practice **Berlin**
- Doctor's Practice **Hannover**
- Doctor's Practice **Lehrte**
- Doctor's Practice **Schwerin**
- Doctor's Practice **Würselen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/08/05**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. Male and female patients ≥ 18 years
2. Diagnosis of tumor disease for which a chemotherapy with Docetaxel Omnicare is indicated
3. Investigator's decision (independent of study participation) to treat the patient with Docetaxel Omnicare®
4. Sufficient patient's compliance upon investigator's assessment
5. Written informed consent of the patient to retrospective and prospective pseudonomized documentation, to forwarding and analysis of the data and to access to the data within monitoring

Exclusion criteria

None

Addresses

- **Primary Sponsor**

  OMNICARE Pharma GmbH
  Ms. Dr. Christine Schneider
  Feringastr. 7
  85774 Unterföhring
  Germany

  Telephone: **+49 89 411 896-1003**
  Fax: **+49 89 411 896-1013**
  E-mail: **C.Schneider at omnicare.de**
  URL: **www.omnicare.de**

- **Contact for Scientific Queries**

  Praxis Drs. Losem/Plewe
  Mr. Dr. med. Christoph Losem
  Am Hasenberg 44
  41462 Neuss
  Germany

  Telephone: **02131 - 10 12 06**
  Fax: **02131 - 10 20 96**
  E-mail: **losem at plelo.de**
  URL: **[---]***

- **Contact for Public Queries**

  Institut Dr. Schauerte
  Mr. Martin Orlovius
  Finkenstr. 7
  80333 München

Contact for Public Queries

Institut Dr. Schauerte
Mr. Martin Orlovius
Finkenstr. 7
80333 München
Germany

Telephone: **089/6418040**
Fax: **089/6415272**
E-mail: **martin.orlovius at dr-schauerte.de**
URL: **www.dr-schauerte.de**

Sources of Monetary or Material Support

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

OMNICARE Pharma GmbH
Ms. Dr. Christine Schneider
Feringastr. 7
85774 Unterföhring
Germany

Telephone: **+49 89 411 896-1003**
Fax: **+49 89 411 896-1013**
E-mail: **C.Schneider at omnicare.de**
URL: **www.omnicare.de**

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.*