Trial Description

Title

Characteristics related to Assessments of disease, patient and treatment associated with long-term survival in ovarian cancer patients (CAROLIN)- Intergroup study NOGGO/ A-AGO

Trial Acronym

NOGGO ov45

URL of the trial

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Brief Summary in Lay Language

The aim of this study is to gather long-term experience from ovarian cancer patients receiving treatment with Niraparib. Patients who live longer than 5 years after diagnosis are designated as long-term survivors in our study. To record the quality of life different questionnaires are used.

Brief Summary in Scientific Language

In this Non-interventional study (NIS) patients with platin-sensitive relapsed ovarian cancer (OC) will be included who are eligible for Niraparib treatment (treatment decision by physician independently before inclusion of the patients into the study). The Niraparib treatment will be according to SmPC. During the NIS study data will be collected at baseline and every six months for up to seven years follow-up (long term survival) or patient's death whatever comes first.

Organizational Data

- DRKS-ID: **DRKS00017371**
- Date of Registration in DRKS: **2019/05/22**
- 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.: **EA4/184/18 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **C56 - Malignant neoplasm of ovary**

Interventions/Observational Groups

- Arm 1: **Data about treatment and medical history will be collected from each patient. Approximately every 3 months, medical data is collected and documented. This is done during their routine examination. In addition to the routine, patients should complete questionnaires at baseline, during Niraparib maintenance therapy and at the end of observation.**

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): **N/A**

Primary Outcome

Identification of disease, patient and treatment factors associated with long term survival. The quality of life is recorded by means of questionnaires, which are completed at each visit (during treatment with Niraparib every 3 months) to the end of treatment (4 weeks after the last dose of Niraparib).

Secondary Outcome

• Evaluation of therapy management of Niraparib with focus on long term survival (including dose, adverse events, duration of treatment, QoL)
• Identification of Niraparib specific factors associated with long-term survival (<5 vs >5 years)

Countries of recruitment

- DE **Germany**
- AT **Austria**

Locations of Recruitment

- University Medical Center **Charité , Berlin**
- Medical Center **Asklepios Klinik Barmbek, Hamburg**
- University Medical Center **Magdeburg**
- other **Medizinisches Versorgungszentrum MediaVita GmbH, Münster**
- Medical Center **Städtisches Klinikum , Karlsruhe**
- Medical Center **Universitätsfrauenklinik, Bonn**
- Doctor's Practice **Fürstenwalde**
- University Medical Center **Innsbruck**
- University Medical Center **Düsseldorf**
- Medical Center **Caritas-Krankenhaus St. Josef, Regensburg**
- Medical Center **Krankenhaus der Barmherzigen Brüder, Graz**
- University Medical Center **Medizinische Uni Wien, Wien**
- Medical Center **Ordensklinikum Linz GmbH Barmherzige Schwestern , Linz**
- Medical Center **Diakonissenkrankenhaus , Mannheim**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/06/01**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

• Female, age at least 18 years
• Participant must be able to understand the study procedures and agree to participate in the study by providing written informed consent

• Histologically diagnosed OC (ovarian carcinoma), fallopian tube cancer or primary peritoneal cancer
• For the last chemotherapy course prior to inclusion in the NIS the patient must have achieved a partial (PR) or complete (CR) tumor response
• Patients eligible for Niraparib maintenance therapy according to SmPC
• Patient is able to take oral medications

Exclusion criteria

• Known hypersensitivity to the components of the product
• Pregnant or breast-feeding patients

Addresses

■ **Primary Sponsor**

Nord-Ostdeutsche Gesellschaft für Gynäkologische Onkologie - NOGGO e.V. c/o Charité Universitätsmedizin Berlin Campus Virchow-Klinikum Klinik für Gynäkologie
Augustenburger Platz 1
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■ **Contact for Scientific Queries**

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- **Collaborator, Other Address**

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Steinbacher Hohl 2-26
60488 Frankfurt am Main
Germany

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

Sources of Monetary or Material Support

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

TESARO Bio Germany GmbH
Leopoldstr. 37A
80802 München
Germany

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

Status

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

Trial Publications, Results and other documents

■ trial protocol (mandatory for transfer to Studybox) **Protokoll_CAROLIN**

** 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.*