Trial Description

Title

Development and prospective validation of a Frailty Score for chemotherapy associated toxicity in Relapsed Ovarian Cancer

Trial Acronym

FraStrROC

URL of the trial

[---]*

Brief Summary in Lay Language

Development and test of a scoreincluding side effects in relapsed cvarian cancer

Brief Summary in Scientific Language

Development and prospective validation of a Frailty Score for chemotherapy associated toxicity in Relapsed Ovarian Cancer

Organizational Data

- DRKS-ID: **DRKS00015667**
- Date of Registration in DRKS: **2018/10/17**
- 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.: **EA4/108/17 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Using questionnaires and assessments (clock draw test, Stand uo and go test, handcraft test) a fragility score will be established**

Characteristics

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

Primary Outcome

Score Evaluation and validation in two phases using questionnaires and assessments

Secondary Outcome

• Adverse events
• The time to symptom deterioration (TUDD)
• Response rate (CR, PR) according to institutional criteria for evaluation (CT/MRI evaluation and / or GCIG criteria), and/or according deterioration or recovery of clinical symptoms
• Progression free survival (PFS) and overall survival (OS) 12 months after start of therapy
• The percentage of patients who complete 4 or more cycles of treatment
• Associations between study assessments, symptom benefit, toxicity and their relation to therapy-free interval and outcome
• The proportion of women who receive treatment because they were (a) symptomatic, (b) have rising tumor markers alone, or (c) have CT/MRI evidence of disease progression
• Rate of emergency hospitalisation
• Need for the use of ESF and G-CSF factors

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Charite-CVK, Berlin**
- Medical Center **Ostalb Kliniken, Mutlangen**
- Medical Center **Paracelsus Medizinischen Privatuniversität , Nürnberg**
- Medical Center **Helios, Wiesbaden**
- Medical Center **Universitätsmedizin, Tübingen**
- Medical Center **UFK, Rostock**
- Doctor's Practice **Hildesheim**
- Medical Center **Uniklinik, Köln**
- Medical Center **Kliniken Essen Mitte Evang. Huyssens-Stiftung/Knappschaft GmbH, Essen**
- Medical Center **Fulda**
- Medical Center **ViDia Christliche Kliniken , Karlsruhe**
- Doctor's Practice **Landshut**
- Medical Center **St. Franziskus Hospital, Münster**
- Medical Center **Carl-Thiem Klinikum, Cottbus**
- Doctor's Practice **Braunschweig**
- Medical Center **Universitätsklinikum Carl Gustav Carus, Dresden**
- Medical Center **Thüringen Kliniken Georgius Agricola GmbH , Saalfeld**
- Doctor's Practice **Bonn**
- Medical Center **Universitätsmedizin Greifswald, Greifswald**
- Doctor's Practice **Fürstenwalde**
- Doctor's Practice **Berlin**
- Medical Center **Katholisches Marienkrankenhaus , Hamburg**
- Medical Center **Klinikum Esslingen, Esslingen am Neckar**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/05/23**
- Target Sample Size: **408**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

• Patients must provide written informed consent prior to performance of study specific assessments and must be willing to comply with recommended treatment and follow up assessments.
• Able to complete questionnaires independently.
• Women aged ≥ 18 years
• Histologically confirmed diagnosis of epithelial ovarian cancer or carcinosarcoma (EOC), primary peritoneal carcinoma (PPC) or fallopian tube cancer (FTC).
• Patients must have recurrent cancer disease (CA 125, radiological or clinical signs of recurrence or progression).
• Patients recommended for monochemotherapy with either Paclitaxel, PLD, Topotecan or Treosulfan and with optional use of bevacizumab according decision of the treating physician and following approval and who should start therapy within 2 week of registration in this trial.
• At least 1 prior treatment regimen for ovarian cancer (i.e. up from second line treatment is allowed)
• Eastern Cooperative Oncology Group (ECOG) performance status of 0 - 3
• A life expectancy of at least 12 weeks.

Exclusion criteria

• Patients recommended for combination chemotherapy or under maintenance treatment after prior chemotherapy, or planned only for radiation therapy.
• Chemotherapy or radiation therapy or tumour embolization within 2 weeks prior to registration and study assessment.
• Biological therapy, immunotherapy, hormonal therapy or treatment with an investigational agent within 21 days.
• Any unstable or serious concurrent condition (e.g. active infection requiring systemic therapy).
• Legal incapacity or limited legal capacity
• Medical or psychological conditions that would not permit the subject to complete the study assessments or sign informed consent

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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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.*