PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

**Identifikation of parameters for the development of a Score to predict the non-compliance of patients with recurrent ovarian cancer undergoing a routine therapy with Ovastat(R).
A non-interventional observation trial (NIS)**

Trial Acronym

SCORE trial

URL of the trial

http://none

Brief Summary in Lay Language

Patients suffering from ovarian cancer often interrupt their chemotherapy after only one or two cycles of therapy. In this cases it is unlikely that patients will benefit from the therapy. The aim of this trial is to to develop a score for the prediction of an early therapy discontinuation based on data from questionaires and clinical examinations. This data will be collected before the therapy starts. Once developed, the score can support physicians and patients to decide for or against another line of chemotherapy.

Brief Summary in Scientific Language

**Based on routine clinical examintions (anamnesis, general condition, laboratory parameters) and supported by different questionaires concerning previous therapy, expectation on therapy, symptoms of disease (MOST questionaire) and stance on complementary medicine (AKKOM questionair) data from 500 patiens with recurrent ovarian cancer are collected in a non interventional trial.
A treatment with treosulfan (Ovastat(R)) was planned before entering the trial for all patients included. The aim of the trial is to explore the correlations between the collected data and an early discontinuation of therapy and to develop a score based on this correlations. The decision for or against a treosulfan therapy can be supported by the Score so that in case of a high probability of early therapy discontinuation the stress for the patient by another chemotherapy line can be avoided.**

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00011344**
- Date of Registration in DRKS: **2016/11/21**
- 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.: **EA2/005/16 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Patients suffering from reccurend ovarian cancer are treated with treosulfan in a non-interventional trial. As treosulfan is approved and can be administered in an intravenous and an oral formulation as well, treosulfan can be used in this trial in both formulations according to patients and physicians preference.**
  The dosage is: i.v. treosulfan: 7.000 mg/m2,q3w oder q4w (both time intervalls are according to approval) - alternative : treosulfan oral, 400-600mg/m2 per day for 28 days, q56d
  - in a recent trial, currently in print, Sehouli et.al. could prove equal efficacy for oral and intravenous treosulfan. [A phase III, open label, randomized multicenter controlled trial of oral versus intravenous Treosulfan in heavily pretreated recurrent ovarian cancer: A study of the North-Eastern German Society of Gynecological Oncology (NOGGO); Journal of Cancer Research and Clinical Oncology in press]
  before starting the treatment, Patients answer questionaries concerning cancer realted quesstions (MOST questionary), therapyexpierience and -expectation and attitude towards complementary medicine (AKKOM questionary).

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

Identifikation of parameters for the development of a Score to predict the non-compliance of patients with recurrent ovarian cancer undergoing a routine therapy with treosulfan (Ovastat(R)).

Secondary Outcome

evalution of preference for a i.v. or oral therapy and reasons for the decision
- dose intensity and duration of treatment
- reasons for therapy discontinuation and dose modification
- tolerability
- concurrent medication
- influence of comarbidity and age on therapy efficacy and and intensity
- determination of objective response (PR+CR) and clinical Benifit (CR+PR+SD)
- median progressiondree Survival (PFS)
- PFS rate after one year
- Time to treatment failure (TTF)
- one Year survival rate
- Subgroup analyses: age <65 and age>65
- previous and subsequent therapies
- relation beteween Therapy compliance and efficacy

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Freiburg im Breisgau**
- Medical Center **Agaplesion Ev. Klinikum Schaumburg, Obernkirchen**
- Doctor's Practice **Hannover**

- Doctor's Practice **Nordhorn**
- Doctor's Practice **Stolberg**
- Medical Center **Friederikenstift, Hannover**
- Medical Center **Kreiskrankenhaus Torgau "Johann Kentmann" gGmbH, Torgau**
- University Medical Center **Universität des Saarlandes Campus Saarbrücken, Homburg**
- Doctor's Practice **Naunhof**
- Doctor's Practice **Hannover**
- Medical Center **Städt. Klinikum Karlsruhe, Karlsruhe**
- Doctor's Practice **Leer**
- Doctor's Practice **Würselen**
- Doctor's Practice **Heidelberg**
- Medical Center **Schwarzwald-Baar Klinikum Villingen-Schwenningen GmbH, Villingen-Schwenningen**
- Medical Center **Klinikum Kassel GmbH, Kassel**
- Doctor's Practice **Mannheim**
- Doctor's Practice **Westerstede**
- Medical Center **Agaplesion Diakonieklinikum Rotenburg GmbH, Rotenburg/Wümme**
- Medical Center **Ortenau Klinikum Offenburg-Gengenbach, Offenburg**
- University Medical Center **Universitätsklinik Carl Gustav Carus der Technischen Universität Dresden, Dresden**
- University Medical Center **Universitätsklinikum Jena, Jena**
- University Medical Center **Universitätsklinikum Schleswig-Holstein, Kiel**
- Medical Center **Klinikum Ansbach, Ansbach**
- University Medical Center **Universitätsklinikum Ulm, Ulm**
- Medical Center **Medius Kliniken Ostfildern Ruit GmbH, Ostfildern**
- Medical Center **Medius Klinik Nürtingen, Nürtingen**
- Doctor's Practice **Remscheid**
- Medical Center **Diako Ev. Diakonie-Krankenhaus gGmbH, Bremen**
- University Medical Center **Charité - Universitätsmedizin Berlin, Berlin**
- Medical Center **Kommunalunternehmen Klinikum Augsburg, Augsburg**
- Medical Center **Klinikum Osnabrück, Osnabrück**
- Medical Center **Elisabeth Krankenhaus Essen, Essen**
- Doctor's Practice **Bielefeld**

- Doctor's Practice **Mühlheim an der Ruhr**
- Medical Center **Kreiskrankenhaus Freudenstadt, Freudenstadt**
- Medical Center **Helios Klinikum Krefeld, Krefeld**
- University Medical Center **Greifswald**
- Doctor's Practice **Bonn**
- Medical Center **Klinikverbund Südwest, Böblingen**
- Medical Center **Evangelisches Krankenhaus Bergisch Gladbach, Bergisch Gladbach**
- other **OnkoLog Moers GbR, Moers**
- other **Apel Medconsult GmbH, Witterda**
- Medical Center **Franziskus Hospital, Bielefeld**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/08/15**
- Target Sample Size: **500**
- 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 with recurrent ovarian cancer who have decided to undergo a chemotherapy with treosulfan
- patients aged 18 years or older
- patients who are able to answer questionaires in german language
- willingness to answer questionaires
- before entering the trial informed consent and data privacy statement must be signed by the patient

Exclusion criteria

contemporaneous partizipation in a different clinical trial during the time of treatment or within the last 30 days.
- hypersensitivity to treosulfan
- patients with missing or reduced legal competence
- patients in an instituion due to a legal or governmental order
- pregnant and breast-feeding women

- no anamnesis form (contains only data collected in routine anamnesis)

Addresses

- **Primary Sponsor**

  medac Gesellschaft für klinische Spezialpräparate mbH
  Theaterstraße 6
  22880 Wedel
  Germany

  Telephone: **+49 4103 8006 0**
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- **Collaborator, Other Address**

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  D-13353 Berlin
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Sources of Monetary or Material Support

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

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URL: **www.medac.de**

Status

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

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum_Score_20160205**
- trial protocol (mandatory for transfer to Studybox) **Beobachtungsplan**

** 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.*