PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

A Randomized Multicenter Study to Compare the Efficacy of Additional Tumor Debulking Surgery vs Chemotherapy Alone in Recurrent Platinum-Sensitive Ovarian Cancer

Trial Acronym

DESKTOP III

URL of the trial

[---]*

Brief Summary in Lay Language

It is still not clear whether a positive AGO-score just selects patients with less aggressive biologic tumor behavior who as well would have had a positive outcome by chemotherapy only, or , if it is a score selecting patients who really benefit from surgery. Nevertheless, the AGO-score was confirmed to select patients with a less than 30% risk of ending with residual tumor after surgery for recurrent disease. This could avoid including patients into the present surgical protocol who could not benefit from an operationThe goal of this third DESKTOP study is to evaluate in a prospectively randomized multicentre setting, whether maximum effort of cytoreductive surgery followed by platinum based combination chemotherapy can improve overall survival as compared to platinum based combination chemotherapy alone in AGO-score positive patients.

Brief Summary in Scientific Language

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Organizational Data

- DRKS-ID: **DRKS00003940**
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Date of Registration in DRKS: **2012/11/30**

- Date of Registration in Partner Registry or other Primary Registry: **2010/07/16**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01166737 (ClinicalTrials.gov)**
- Sponsor-ID: **AGO-OVAR OP.4 DESKTOP III (AGO Study Group)**

Health condition or Problem studied

- Free text: **Fallopian Tube Cancer**
- Free text: **Ovarian Cancer**
- Free text: **Peritoneal Cavity Cancer**
- ICD10: **C56 - Malignant neoplasm of ovary**
- ICD10: **C78.6 - Secondary malignant neoplasm of retroperitoneum and peritoneum**
- ICD10: **C57.0 - Malignant neoplasm: Fallopian tube**

Interventions/Observational Groups

- Arm 1: **Procedure: Tumor Debulking Surgery (surgery in recurrent ovarian disease)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

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

Control: **Control group receives no treatment**

Purpose: **[---]***

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

Primary Outcome

- Overall survival in patients with platinum-sensitive recurrent ovarian cancer with a positive AGO-score; time frame: Approximately 36 months after last patient randomized and observation of 244 events

Secondary Outcome

- Quality of Life; time frame: Baseline, 6, and 12 months after randomization; EORTC QLQ 30 and FACT NCCN Ovarian Symptom Index
- Progression free survival; time frame: Progression free survival is defined as interval between date of randomization and 2nd relapse/progression or death (whatever occurs first).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Ostalbklinikum, Aalen**
- **Charité - Universitätsmedizin Berlin, Campus Virchow-Klinikum, Klinik für Frauenheilkunde, Berlin**
- <style fontName='DejaVu Sans' isBold='true'>Univerisity Hospital; Dept. of Gynecology & Obstetrics, Erlangen</style>
- <style fontName='DejaVu Sans' isBold='true'>University hospital, Dept. of gynecology & obstetrics, Essen</style>

- **Kliniken Essen Mitte, Evang. Huyssens-Stiftung, Essen**
- **Klinikum Esslingen, Esslingen**
- **Klinikum der JWG Universität Frankfurt, Frankfurt am Main**
- **Universitätsklinikum Freiburg, Frauenklinik, Freiburg**
- **Gynecologic Clinic of the Ernst-Moritz-Arndt-University, Greifswald**
- **Medizinische Hochschule, Hannover**
- **Universitätsklinikum Schleswig-Holstein Campus Kiel, Klinik f. Gynäkologie u. Geburtshilfe, Kiel**
- **Klinikum der Philipps-Universität Marburg, Klinik für Gynäkologie, Gynäkologische Endokrinologie, Marburg**
- **St. Josefsklinik, Offenburg**
- **St. Vincenz-Krankenhaus, Paderborn**
- **Klinikum Südstadt, Rostock**
- **Universitätsklinikum, Universitätsfrauenklinik, Ulm**
- **HSK, Dr. Horst Schmidt Klinik GmbH, Wiesbaden**
- **Klinikum der Stadt Wolfsburg, Wolfsburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/07/31**
- 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

Inclusion criteria:

- Patients with first recurrence of platinum sensitive, invasive epithelial ovarian-, fallopian tube- or primary peritoneal cancer of any initial stage.

- Progression-free interval of at least 6 months after end of last platinum-containing therapy, or recurrence within 6 months or later after primary surgery if

the patient
has not received prior chemotherapy in patients with FIGO I. Non cytostatic
maintenance therapy not containing platinum will not be considered for this
calculation.

- A positive AGO-score. Obligatory requirements for a positive AGO recurrence score in
platinum-sensitive disease:

1. Performance status ECOG 0

2. No residual tumor after primary surgery (if unknown, alternatively primary FIGO
stage I/II). If report from 1st surgery is not available contact study chairman
who will decide whether inclusion is possible or not.

3. Absence of ascites (cut off < 500 ml: radiological or ultrasound estimation)

- Complete resection of the tumor by median laparotomy seems possible

- Patients who have given their signed and written informed consent and their consent
to data transmission and -processing.

Exclusion criteria

Exclusion Criteria:

- Patients with non-epithelial tumors as well as borderline tumors.

- Patients without recurrence who are scheduled for diagnostic/second-look surgery or
debulking surgery after completion of chemotherapy

- More than one prior chemotherapy

- Patients with second, third, or later recurrence

- Patients with second malignancies who have been treated by laparotomy, as well as
other neoplasms, if the treatment might interfere with the treatment of relapsed
ovarian cancer or if major impact on prognosis is expected.

- Patients with so-called platinum-refractory tumor, i.e. progression during chemotherapy or recurrence within 6 months after end of former first platinum-containing therapy

- Only palliative surgery planned

- Radiological signs suggesting metastases not accessible to surgical

removal (i.e. complete resection is deemed impossible)

- **Any concomitant disease not allowing surgery and/or chemotherapy**
- **Any medical history indicating excessive peri-operative risk**
- **Any current medication inducing considerable surgical risk (e.g. bleeding: due to oral anticoagulating agents, bevacizumab)**

Addresses

- **Primary Sponsor**

  AGO Study Group

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Scientific Queries**

  Philipp Harter, MD

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- **Contact for Public Queries**

  Philipp Harter, MD

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  URL: **[---]***
- **Collaborator, Other Address**

  ARCAGY/ GINECO GROUP

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Collaborator, Other Address**

  MITO

Collaborator, Other Address

MITO

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- **Collaborator, Other Address**

  Arbeitsgemeinschaft Gynaekologische Onkologie Austria

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

- **Collaborator, Other Address**

  GlaxoSmithKline

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

- **Collaborator, Other Address**

  medac GmbH

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

Sources of Monetary or Material Support

- **[---]***

  Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

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

Status

- Recruitment Status: **Recruiting ongoing**
-

Deutsches Register Klinischer Studien
German Clinical Trials Register

Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.

- Translation on version: 7

- Last processed date by ClinicalTrials.gov: 2013/10/30

* *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.*