Trial on Radical Upfront Surgery in Advanced Ovarian Cancer (TRUST)

This study is currently recruiting participants. (see Contacts and Locations)

Verified October 2016 by AGO Study Group

Sponsor:
AGO Study Group

Information provided by (Responsible Party):
AGO Study Group

ClinicalTrials.gov Identifier:
NCT02828618

First received: June 30, 2016
Last updated: October 10, 2016
Last verified: October 2016
History of Changes

Purpose

This study consists of three parts, whereas Part 1 and Part 2 are performed in Germany only, and Part 3 is a multinational trial.

All patients with suspicion of advanced ovarian cancer are detected in the participating study centers in a pre-screening. The study centers will register all patients with suspected ovarian cancer in a screening log. After the patients have given informed consent, they can be enrolled in different parts of the study.

TRUST-Trial: This part compares two strategies in the therapy of advanced ovarian cancer. En detail, this part of the trial will evaluate if one of two strategies of timing surgery within the therapeutic procedures may show any significant advances in terms of overall survival over the other.

Condition	Intervention
Ovarian Cancer	Procedure: PDS Drug: 6 cycles of standard chemotherapy Drug: 3 cycles of standard NACT Procedure: IDS Drug: 3 cycles of standard chemotherapy

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Trial on Radical Upfront Surgery in Advanced Ovarian Cancer

Resource links provided by NLM:

Genetics Home Reference related topics: ovarian cancer

MedlinePlus related topics: Ovarian Cancer

Genetic and Rare Diseases Information Center resources: Ovarian Cancer

U.S. FDA Resources

Further study details as provided by AGO Study Group:

Primary Outcome Measures:

- overall survival (OS) [Time Frame: Patients will be followed up for a minimum of 5 years after registration/randomisation or until death]

  To compare the overall survival (OS) after primary debulking surgery (PDS) versus interval debulking surgery (IDS) following neoadjuvant chemotherapy (NACT) in patients with FIGO (2014) stage IIIB-IVB ovarian, tubal, and peritoneal carcinoma. The primary endpoint overall survival time is calculated from the date of randomization until the date of death from any cause or date of last contact (censored observation).

Secondary Outcome Measures:

- Progression-free survival (PFS) [Time Frame: Patients will be followed up for a minimum of 5 years after registration/randomisation or until death]

  Progression-free survival time is calculated from the date of randomization until the date of first progressive disease or death, whichever occurs first or date of last contact (censored observation). Progressive disease is defined as clinical or imaging-detected tumor progression or death in cases without prior documented tumor progression.

- Progression-free survival 2 (PFS2) [Time Frame: Patients will be followed up for a minimum of 5 years after registration/randomisation or until death]

  PFS2 time is calculated from the date of randomization until the date of second progressive disease or death, whichever occurs first or date of last contact (censored observation).

- Time to first subsequent anticancer therapy or death (TFST) [Time Frame: Patients will be followed up for a minimum of 5 years after registration/randomisation or until death]

  Time to first subsequent anticancer therapy is calculated from the date of randomization until the starting date of the first subsequent anticancer therapy or death, whichever occurs first or date of last contact (censored observation). Maintenance treatments following a cytostatic treatment are not considered separate treatment lines.

- Time to second subsequent anticancer therapy or death (TSST) [Time Frame: Patients will be followed up for a minimum of 5 years after registration/randomisation or until death]

  Time to second subsequent anticancer therapy is calculated from the date of randomization until the starting date of the second subsequent anticancer therapy or death, whichever occurs first or date of last contact (censored observation). Maintenance treatments following a cytostatic treatment are not considered separate treatment lines.

- Quality of life (QoL) [Time Frame: Patients will be followed up for a minimum of 5 years after registration/randomisation or until death]

  Quality of life (QoL) as measured by EORTC QLQ-C30 (Version 3), EORTC QLQ-OV28, EQ-5D-3L

- Documentation of surgical complications [Time Frame: Patients will be followed up for 1 year after surgery or until death]

  Assessment of safety: documentation of surgical complications 28 days after surgery and 1 year after surgery.

Estimated Enrollment:	686
Study Start Date:	July 2016
Estimated Study Completion Date:	April 2023
Estimated Primary Completion Date:	April 2023 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Arm I PDS and chemotherapy PDS with maximum effort to achieve the goal of complete gross resection then followed by 6 cycles of standard chemotherapy	Procedure: PDS PDS with maximum effort to achieve the goal of complete gross resection Drug: 6 cycles of standard chemotherapy 6 cycles of standard chemotherapy after PDS
Experimental: Arm II NACT, IDS and chemotherapy 3 cycles of standard NACT followed by IDS with maximum effort to achieve the goal of complete gross resection followed by 3 more cycles (for a total of 6) of standard chemotherapy	Drug: 3 cycles of standard NACT 3 cycles of standard NACT Procedure: IDS IDS with maximum effort to achieve the goal of complete gross resection after NACT Drug: 3 cycles of standard chemotherapy 3 more cycles (for a total of 6) of standard chemotherapy after IDS

Show Detailed Description

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- suspected or histologically confirmed, newly diagnosed invasive epithelial ovarian cancer FIGO stage IIIB-IV (IV only if resectable metastasis)

- Females aged ≥ 18 years
- Patients who have given their written informed consent
- Good performance status (ECOG 0/1)
- Good ASA score (1/2)
- Preoperative CA 125/CEA ratio ≥ 25 (if CA-125 is elevated)*
- If <25 and/or biopsy with non-serous, non-endometroid histology, esophago-gastro-duodenoscopy (EGD) and colonoscopy mandatory to exclude gastrointestinal primary cancer
- Assessment of an experienced surgeon, that based on all available information, the patient can undergo the procedure and the tumor can potentially be completely resected
- Adequate bone marrow function: Absolute neutrophil count (ANC) ≥ 1.5 x 109/L. This ANC cannot have been induced or supported by granulocyte colony stimulating factors.
- Platelet count ≥ 100 x 109/L.
- Renal function: Serum-Creatinine ≤ 1.5 x institutional upper limit normal (ULN).
- Hepatic function:
  - Bilirubin ≤ 1.5 x ULN.
  - SGOT ≤ 3 x ULN
  - Alkaline phosphatase ≤ 2.5 x ULN.
- Neurologic function: Neuropathy (sensory and motor) less than or equal to CTCAE Grade 1.

Exclusion Criteria:

- Non epithelial ovarian malignancies and borderline tumors
- Secondary invasive neoplasms in the last 5 years (except synchronal endometrial carcinoma FIGO IA G1/2, non melanoma skin cancer, breast cancer T1 N0 M0 G1/2) or with any signs of relapse or activity.
- Recurrent ovarian cancer
- Prior chemotherapy for ovarian cancer or abdominal/pelvic radiotherapy
- Unresectable parenchymal lung metastasis, liver metastasis or bulky lymph-nodes in the mediastinum in CT chest and abdomen/pelvis
- Clinical relevant dysfunctions of blood clotting (including drug induced)
- Any significant medical reasons, age or performance status that will not allow to perform the study procedures (estimation of investigator)
- Pregnancy
- Dementia or significantly altered mental status that would prohibit the understanding and giving of informed consent
- Any reasons interfering with regular follow-up

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02828618

Contacts

Contact: Gabriele Elser +496118804670 office-wiesbaden@ago-ovar.de

Locations

Germany

Charité - Universitätsmedizin Berlin, Campus Virchow Klinikum, Klinik für Gynäkologie Berlin, Germany, 13353	**Recruiting**
Universitätsklinikum Carl Gustav Carus Dresden, Klinik & Poliklinik f. Frauenheilkunde & Geburtshilfe Dresden, Germany, 01307	**Not yet recruiting**
Kliniken Essen-Mitte, Evang. Huyssens-Stiftung, Klinik für Gynäkologie und gyn. Onkologie Essen, Germany, 45136	**Recruiting**
Universitätsklinikum Hamburg-Eppendorf, Klinik und Poliklinik für Gynäkologie Hamburg, Germany, 20246	**Recruiting**
Klinik und Poliklinik für Frauenheilkunde und Geburtshilfe, Klinikum der Universität München München, Germany, 81377	**Recruiting**
Klinikum rechts der Isar, Frauen- und Poliklinik München, Germany, 81675	**Not yet recruiting**

United Kingdom

Imperial College London, Hammersmith Hospital, Surgery&Cancer	**Not yet recruiting**

London, United Kingdom, W12 OHS

Sponsors and Collaborators

AGO Study Group

Investigators

Principal Investigator: Sven Mahner, Professor MD AGO Study Group

More Information

Responsible Party:	AGO Study Group
ClinicalTrials.gov Identifier:	NCT02828618 History of Changes
Other Study ID Numbers:	AGO-OVAR OP.7/TRUST
Study First Received:	June 30, 2016
Last Updated:	October 10, 2016
Individual Participant Data Plan to Share IPD:	Undecided

Additional relevant MeSH terms:

Ovarian Neoplasms	Genital Diseases, Female
Endocrine Gland Neoplasms	Genital Neoplasms, Female
Neoplasms by Site	Urogenital Neoplasms
Neoplasms	Endocrine System Diseases
Ovarian Diseases	Gonadal Disorders
Adnexal Diseases	

ClinicalTrials.gov processed this record on January 24, 2017