

Trial record **16 of 4309** for: TRUST
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Trial on Radical Upfront Surgery in Advanced Ovarian Cancer (TRUST)

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

Verified August 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: August 19, 2016

Last verified: August 2016

[History of Changes](#)

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Tracking Information

First Received Date ICMJE	June 30, 2016
Last Updated Date	August 19, 2016
Start Date ICMJE	July 2016
Estimated Primary Completion Date	April 2023 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE (submitted: July 7, 2016)	<p>overall survival (OS) [Time Frame: Patients will be followed up for a minimum of 5 years after registration/randomisation or until death] [Designated as safety issue: No]</p> <p>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.</p> <p>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).</p>
Original Primary Outcome Measures ICMJE	Same as current
Change History	Complete list of historical versions of study NCT02828618 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE (submitted: July 7, 2016)	<ul style="list-style-type: none"> Progression-free survival (PFS) [Time Frame: Patients will be followed up for a minimum of 5 years after registration/randomisation or until death] [Designated as safety issue: No] <p>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.</p> <ul style="list-style-type: none"> Progression-free survival 2 (PFS2) [Time Frame: Patients will be followed up for a minimum of 5 years after registration/randomisation or until death] [Designated as safety issue: No] <p>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).</p> <ul style="list-style-type: none"> 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] [Designated as safety issue: No] <p>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.</p> <ul style="list-style-type: none"> 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] [Designated as safety issue: No]

	<p>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.</p> <ul style="list-style-type: none"> Quality of life (QoL) [Time Frame: Patients will be followed up for a minimum of 5 years after registration/randomisation or until death] [Designated as safety issue: No] <p>Quality of life (QoL) as measured by EORTC QLQ-C30 (Version 3), EORTC QLQ-OV28, EQ-5D-3L</p> <ul style="list-style-type: none"> Documentation of surgical complications [Time Frame: Patients will be followed up for 1 year after surgery or until death] [Designated as safety issue: Yes] <p>Assessment of safety: documentation of surgical complications 28 days after surgery and 1 year after surgery.</p>
Original Secondary Outcome Measures ICMJE	<i>Same as current</i>
Current Other Outcome Measures ICMJE	<i>Not Provided</i>
Original Other Outcome Measures ICMJE	<i>Not Provided</i>
Descriptive Information	
Brief Title ICMJE	Trial on Radical Upfront Surgery in Advanced Ovarian Cancer
Official Title ICMJE	Trial on Radical Upfront Surgery in Advanced Ovarian Cancer
Brief Summary	<p>This study consists of three parts, whereas Part 1 and Part 2 are performed in Germany only, and Part 3 is a multinational trial.</p> <p>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.</p> <p>TRUST-Trial: This part compares two strategies in the therapy of advanced ovarian cancer. In 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.</p>
Detailed Description	<p>Both randomised groups are treated with surgery for complete resection following guideline recommendations and including median laparotomy, complete adhesiolysis, hysterectomy, bilateral salpingo-oophorectomy, omentectomy and (partial) resection of all affected organs (e.g. small or large bowel, peritoneum, spleen, pancreas, peritoneum, urinary tract etc.) as well as pelvic and paraaortic lymphadenectomy if indicated. Patients with significant pleural effusion (>500 mL in the right chest or any pleural effusion in the left chest, assessed either through ultrasound or CT scan) need to undergo video assisted thoracoscopy or open assessment of the pleura prior or during debulking surgery to detect and if possible remove intrathoracic disease.</p> <p>Group 1: Primary debulking surgery Patients allocated to the primary debulking group undergo surgery followed by 6 cycles of platinum and taxane based chemotherapy.</p> <p>Recommended systemic treatment Group 1:</p> <p>It is recommended to start systemic treatment after sufficient regeneration from surgery [45], which will be ideally 2 to 6 weeks (but at the latest 8 weeks) after surgery. The following treatments are recommended:</p> <ol style="list-style-type: none"> Participation in a prospective randomized trial, as long as participation is possible in case of randomization in either arm of the current study Carboplatin AUC 5-6 / paclitaxel 175 mg/m² q21 / bevacizumab 15mg/KG q21, 6 cycles followed by bevacizumab maintenance therapy for a total of 15 months or until disease progression. Carboplatin AUC 5-6 / paclitaxel 175 mg/m² q21, 6 cycles. Substitution of paclitaxel by docetaxel (75mg/m²) in cases of contraindications to paclitaxel is possible. Maintenance/consolidation therapy inside prospective trials or according to national standard treatments is allowed. Additional treatment outside prospective studies is not recommended. Carboplatin AUC 5 - 6, q21 , 6 cycles in the case of contraindications of combination chemotherapy <p>Group 2: Interval debulking surgery Patients allocated to the interval debulking surgery group undergo biopsy to confirm ovarian cancer and then 3 cycles of neoadjuvant preoperative platinum and taxane based chemotherapy. Then interval debulking surgery is performed followed by 3 cycles of postoperative platinum and taxane based chemotherapy</p> <p>Recommended systemic treatment Group 2:</p> <p>It is recommended to start systemic treatment as soon as possible after biopsy confirmation of ovarian cancer.</p> <p>The following treatments are recommended for neoadjuvant chemotherapy:</p>

	<ol style="list-style-type: none"> 1. Participation in a prospective randomized trial, as long as participation is possible in case of randomization in either arm of the current study 2. Carboplatin AUC5-6 / paclitaxel 175 mg/m² q21, 3 cycles. Substitution of paclitaxel by docetaxel (75mg/m²) in cases of contraindications to paclitaxel is possible. 3. Carboplatin AUC 5-6, q21 , 3 cycles in the case of contraindications of combination chemotherapy <p>It is recommended to start postoperative chemotherapy after sufficient regeneration from interval debulking surgery, which will be ideally 2 to 6 weeks after surgery. The following treatments are recommended:</p> <ol style="list-style-type: none"> 1. Participation in a prospective randomized trial, as long as participation is possible in case of randomization in either arm of the current study 2. Carboplatin AUC 5-6 / paclitaxel 175 mg/m² q21 / bevacizumab 15mg/KG q21, 3 cycles followed by bevacizumab maintenance therapy for a total of 15 months or until disease progression. 3. Carboplatin AUC5-6 / paclitaxel 175 mg/m² q21, 3 cycles. Substitution of paclitaxel by docetaxel (75mg/m²) in cases of contraindications to paclitaxel is possible. Maintenance/consolidation therapy inside prospective trials or according to national standard treatments is allowed. Additional treatment outside prospective studies is not recommended. 4. Carboplatin AUC 5-6, q21 , 3 cycles in the case of contraindications of combination chemotherapy
Study Type ICMJE	Interventional
Study Phase	<i>Not Provided</i>
Study Design ICMJE	Allocation: Randomized Intervention Model: Parallel Assignment Masking: Open Label Primary Purpose: Treatment
Condition ICMJE	Ovarian Cancer
Intervention ICMJE	<ul style="list-style-type: none"> • 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 • 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
Study Arm (s)	<ul style="list-style-type: none"> • 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 Interventions: <ul style="list-style-type: none"> ◦ Procedure: PDS ◦ Drug: 6 cycles of standard chemotherapy • 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 Interventions: <ul style="list-style-type: none"> ◦ Drug: 3 cycles of standard NACT ◦ Procedure: IDS ◦ Drug: 3 cycles of standard chemotherapy
Publications *	<i>Not Provided</i>
* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.	
Recruitment Information	
Recruitment Status ICMJE	Recruiting
Estimated Enrollment	686

ICMJE					
Estimated Completion Date	April 2023				
Estimated Primary Completion Date	April 2023 (final data collection date for primary outcome measure)				
Eligibility Criteria ICMJE	<p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • 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) $\geq 1.5 \times 10^9/L$. This ANC cannot have been induced or supported by granulocyte colony stimulating factors. • Platelet count $\geq 100 \times 10^9/L$. • Renal function: Serum-Creatinine $\leq 1.5 \times$ institutional upper limit normal (ULN). • Hepatic function: <ul style="list-style-type: none"> ◦ Bilirubin $\leq 1.5 \times$ ULN. ◦ SGOT $\leq 3 \times$ ULN ◦ Alkaline phosphatase $\leq 2.5 \times$ ULN. • Neurologic function: Neuropathy (sensory and motor) less than or equal to CTCAE Grade 1. <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • Non epithelial ovarian malignancies and borderline tumors • Secondary invasive neoplasms in the last 5 years (except synchronous 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 				
Gender	Female				
Ages	18 Years and older (Adult, Senior)				
Accepts Healthy Volunteers	No				
Contacts ICMJE	<table border="1"> <tr> <td>Contact: Gabriele Elser</td> <td>+496118804670</td> <td>office-wiesbaden@ago-ovar.de</td> <td></td> </tr> </table>	Contact: Gabriele Elser	+496118804670	office-wiesbaden@ago-ovar.de	
Contact: Gabriele Elser	+496118804670	office-wiesbaden@ago-ovar.de			
Listed Location Countries ICMJE	Germany, United Kingdom				
Removed Location Countries					
Administrative Information					
NCT Number ICMJE	NCT02828618				
Other Study ID Numbers	AGO-OVAR OP.7/TRUST				

ICMJE	
Has Data Monitoring Committee	Yes
Plan to Share Data	Undecided
IPD Description	<i>Not Provided</i>
Responsible Party	AGO Study Group
Study Sponsor ICMJE	AGO Study Group
Collaborators ICMJE	<i>Not Provided</i>
Investigators ICMJE	Principal Investigator: Sven Mahner, Professor MD AGO Study Group
Information Provided By	AGO Study Group
Verification Date	August 2016
ICMJE Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP	