KURZPROTOKOLL
OReO

Öffentlicher Titel	Phase III Studie zur Olaparib-Erhaltungstherapie bei vorbehandeltem Eierstockkrebs
Wissenschaftl. Titel	A Phase IIIb, Randomised, Double-blind, Placebo-controlled, Multicentre Study of Olaparib Maintenance Retreatment in Patients with Epithelial Ovarian Cancer Previously Treated With a PARPi and Responding to Repeat Platinum Chemotherapy
Kurztitel	OReO
Studienart	prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: Eierstockkrebs (Ovarialkarzinom) - Zweitlinie oder höher

Einschlusskriterien

- Provision of informed consent prior to any study specific procedures
- Female patients => 18 years of age, with histologically diagnosed relapsed non-mucinous epithelial ovarian cancer (EOC) (including primary peritoneal and/or fallopian tube cancer) (Non-mucinous EOC includes patients with serous, endometrioid, and transitional cell tumours, and those with mixed histology where one of these subtypes is predominant (>50%). Inclusion of other subtypes should first be discussed with the Medical Monitor).
- Documented BRCA1/2 status.
- Patients must have received one prior PARPi therapy PARPi therapy includes any agent (including Olaparib) used in a maintenance setting For the BRCA1/2 (+ve) cohort, the duration of first PARPi exposure must have been =>18 months following a first line of chemotherapy or =>12 months following a second or subsequent line of chemotherapy. For the BRCA1/2 (-ve) cohort, the duration of first PARPi exposure must have been =>12 months following a first line of chemotherapy or =>6 months following a second or subsequent line of chemotherapy For the last chemotherapy course immediately prior to randomisation on the study Patients must have received a platinum-based chemotherapy regimen (carboplatin or cisplatin) and have received at least 4 cycles of treatment Patients must have had a partial or complete radiological response to chemotherapy following completion of this course as evaluated by the Investigator Patient may have debulking surgery, or surgery to specific lesions, in addition to chemotherapy, provided that a partial or complete radiological response to chemotherapy is also demonstrated. Patients who have no measurable disease following surgery alone are not eligible Patients must not have received bevacizumab during this course of treatment. Bevacizumab use as part of an earlier line of chemotherapy is permitted Patients must not have received any investigational agent during this course of treatment Patients must be randomised within 8 weeks of their last dose of chemotherapy (last dose is the day of the last infusion)
- Patients must have normal organ and bone marrow function measured within 28 days of randomization.
- Eastern Cooperative Oncology Group performance status 0-1.
- Patients must have a life expectancy =>16 weeks.
- Postmenopausal or evidence of non-childbearing status for women of childbearing potential: negative urine or serum pregnancy test within 28 days of study treatment and confirmed prior to treatment on day 1
- At least one lesion (measurable and/or non-measurable) that can be accurately assessed at baseline with computed tomography (CT) or magnetic resonance imaging (MRI) and is suitable for repeated assessment. or No measurable disease following a complete response to most recent chemotherapy (+/- surgery)
- A formalin fixed, paraffin embedded (FFPE) tumour sample from the cancer of sufficient quantity and quality (as specified in the Covance Central Laboratory Services Manual) must be available for future central testing of tumour genetic status.

	- For inclusion in the optional biomarker research, patients must sign an informed consent for biomarker research.
Ausschlusskriterien	- Involvement in the planning and/or conduct of the study (applies to both AstraZeneca staff and/or staff at the study site). - Participation in another clinical study with an investigational product during the chemotherapy course immediately prior to randomisation. - Other malignancy within the last 5 years except the ones detailed in the exclusion criteria section of study protocol. - Resting electrocardiogram (ECG) with corrected QT interval (QTc) >470 msec on 2 or more time points within a 24 hour period or family history of long QT syndrome6. Patients receiving any systemic chemotherapy or radiotherapy (except for palliative radiotherapy) within 3 weeks prior to study treatment. - Concomitant use of known strong cytochrome P450 (CYP) subfamily 3A (CYP3A) inhibitors or moderate CYP3A inhibitors. - Concomitant use of known strong or moderate CYP3A inducers. - Persistent toxicities (Common Terminology Criteria for Adverse Event [CTCAE] grade 2 or higher) caused by previous cancer therapy, excluding alopecia and stable Grade 2 peripheral neuropathy . - Patients with current or previous myelodysplastic syndrome (MDS)/acute myeloid leukaemia (AML) or with features suggestive of MDS/AML. - Patients with symptomatic uncontrolled brain metastases. - Immunocompromised patients, e.g., patients who are known to be serologically positive for human immunodeficiency virus (HIV). - Patients with a known hypersensitivity to Olaparib or any of the excipients of the product. - Patients with a known active hepatitis (i.e., Hepatitis B or C). - Patient who have received a whole blood transfusion within 30 days prior to screening tests (packed red blood cells and platelet transfusions are acceptable)
Alter	18 Jahre und älter
Molekularer Marker	BRCA
Prüfzentren	**Universitätsmedizin Frankfurt** (Geschlossen) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Christina Wabbels Tel: 069 6301-80429 wabbels@med.uni-frankfurt.de
Sponsor	Astra Zeneca (Hauptsponsor)
Registrierung in anderen Studienregistern	EudraCT 2016-003346-90 ClinicalTrials.gov NCT03106987
Links	Studiendokumente zum Download (roXtra)