

## **KURZPROTOKOLL** **C-Patrol**

<b>Öffentlicher Titel</b>	Nicht interventionelle Studie zu Olaparib bei Ovarialkarzinompatienten mit BRCAm+ und PSR
<b>Wissenschaftl. Titel</b>	A Single Arm, Prospective Non-interventional Study (NIS) to Collect Clinical and Patient Reported Outcome Data in an Olaparib Treated BRCAm+ PSR Ovarian Cancer Population
<b>Kurztitel</b>	C-Patrol
<b>Studienart</b>	multizentrisch, prospektiv, offen/unverblindet, einarmig, Pharma-Studie
<b>Studienphase</b>	nicht zutreffend
<b>Erkrankung</b>	Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: Eierstockkrebs (Ovarialkarzinom) - Zweitlinie oder höher
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Signed written informed consent prior to or at day 1 of olaparib treatment</li><li>- Women aged <math>\geq</math> 18 years</li><li>- Patients with platinum sensitive relapsed high grade epithelial ovarian cancers (including primary peritoneal and/or fallopian tube cancer). (Platinum sensitive disease is defined as disease progression 6 months after completion of their last dose of platinum based chemotherapy. Patients must be currently in response to platinum-based chemotherapy. For the last chemotherapy course immediately prior to enrolment on the study, patients must be, in the opinion of the investigator, in response (partial or complete), following completion of this chemotherapy course.</li><li>- Documented BRCA mutations (germline and/or somatic mutation in BRCA1 (Breast Cancer gene 1) and/or BRCA2 (Breast Cancer gene 2) that is predicted to be deleterious or suspected deleterious (known or predicted to be detrimental/lead to loss of function))</li><li>- Patients should be in line with the specifications mentioned in the German LYNPARZA (olaparib) SmPC (Summary Product Characteristics)</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Known hypersensitivity to olaparib or any of the excipients of the drug</li><li>- Patients who have started olaparib monotherapy for more than 14 days before giving their informed consent</li><li>- Pregnancy or breast feeding</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Molekularer Marker</b>	BRCA
<b>Prüfzentren</b>	<b>Frauenheilkunde und Geburtshilfe</b> (Rekrutierung beendet) Theodor-Stern-Kai 7 60590 Frankfurt am Main Allg. Ansprechpartner der Abteilung Gynäkologie (UCT, UKF) <b>Universitätsklinikum Frankfurt</b> (Rekrutierung beendet) Klinik für Frauenheilkunde und Geburtshilfe Theodor-Stern-Kai 7 60590 Frankfurt am Main Allg. Ansprechpartner der Abteilung Gynäkologie (UCT, UKF)
<b>Sponsor</b>	Astra Zeneca
<b>Förderer</b>	Astra Zeneca
<b>Registrierung in anderen Studienregistern</b>	Deutsches Register Klinischer Studien DRKS00010737 ClinicalTrials.gov NCT02503436
<b>Therapie</b>	Olaparib