

## C-PATROL - Non-interventional Study (NIS) to Collect Clinical and Patient Reported Outcome Data in an Olaparib Treated BRCAm+ PSR Ovarian Cancer Population (C-PATROL)

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

Verified June 2016 by AstraZeneca

**Sponsor:**  
AstraZeneca

**Information provided by (Responsible Party):**  
AstraZeneca

**ClinicalTrials.gov Identifier:**  
NCT02503436

First received: July 8, 2015  
Last updated: June 1, 2016  
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[History of Changes](#)

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[No Study Results Posted](#)

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### Purpose

The main objective of the proposed non-interventional study is to obtain real-world effectiveness, safety and treatment patterns data of patients with BRCAm+ (Breast Cancer Gene(s) mutation positive) platinum sensitive relapsed (PSR) ovarian cancer in German hospitals and outpatient practices treated with olaparib.

#### Condition

"Ovarian Cancer", "Hereditary Ovarian Cancer Syndrome"

Study Type: Observational [Patient Registry]

Study Design: Observational Model: Cohort  
Time Perspective: Prospective

Target Follow-Up Duration: 66 Months

Official Title: C-PATROL - 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

#### Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [ovarian cancer](#)

[MedlinePlus](#) related topics: [Cancer](#) [Ovarian Cancer](#)

[Genetic and Rare Diseases Information Center](#) resources: [Fallopian Tube Cancer](#) [Ovarian Cancer](#)

[U.S. FDA Resources](#)

#### Further study details as provided by AstraZeneca:

##### Primary Outcome Measures:

- To assess clinical effectiveness of olaparib maintenance monotherapy by assessment of progression free survival (PFS) in patients with BRCAm+ ovarian cancer. Methods and time intervals for tumor assessment depend on the investigator's decision. [ Time Frame: Date of first documented dose of olaparib to the date of progression (as judged by the investigator) or death (of any cause) whichever occurred before, assessed approximately up to 66 months ] [ Designated as safety issue: No ]

##### Secondary Outcome Measures:

- To collect and explore real-life data on patient outcomes in terms of Overall Survival (OS) [ Time Frame: Date of first documented dose of olaparib to death of any cause, assessed approximately up to 66 months ] [ Designated as safety issue: No ]
- Time to first subsequent therapy (TFST) [ Time Frame: Date of first documented dose of olaparib to date of first administration of first subsequent therapy or death if this occurs before commencement of first subsequent treatment, assessed approximately up to 66 months ] [ Designated as safety issue: No ]
- Progression-free survival 2 (PFS2) [ Time Frame: Date of first administration of first subsequent therapy to date of progression as assessed by the investigator or death, assessed approximately up to 66 months ] [ Designated as safety issue: No ]
- Time to second subsequent therapy (TSST) [ Time Frame: Date of first documented dose of olaparib to date of first administration of second subsequent therapy or death if this occurs before commencement of second subsequent treatment, assessed approximately up to 66 months ] [ Designated as safety issue: No ]
- Time to discontinuation of olaparib monotherapy (TDO) [ Time Frame: Date of first documented dose of olaparib monotherapy to date of last

documented dose of olaparib monotherapy or death whichever occurred before, assessed approximately up to 66 months ]  
[ Designated as safety issue: No ]

- Assessment of health-related quality of life (HRQoL) in patients undergoing treatment with olaparib [ Time Frame: Date of first visit to last visit. HRQoL are collected every 3 months up to 66 months ] [ Designated as safety issue: No ]

Health related quality of life (HRQoL): Assessment of general cancer-associated and specific ovarian cancer associated parameters by use of standardized HRQoL questionnaires:

- Functional assessment of Cancer Therapy for Patients with Ovarian Cancer (FACT-O)
  - Functional Assessment of Chronic Illness - Fatigue (FACIT-Fatigue)
  - Functional Living Index - Emesis (FLIE)
- Safety of Olaparib: collection of Adverse Events (AE) [ Time Frame: Date of first documented dose of Olaparib to last visit, assessed approximately up to 66 months ] [ Designated as safety issue: Yes ]

Type and frequency of adverse event (AE), intensity, causal relationship to olaparib, outcome, seriousness, management of adverse event

Estimated Enrollment: 300  
Study Start Date: October 2015  
Estimated Study Completion Date: June 2021  
Estimated Primary Completion Date: June 2021 (Final data collection date for primary outcome measure)

## ► Eligibility

Ages Eligible for Study: 18 Years and older  
Genders Eligible for Study: Female  
Accepts Healthy Volunteers: No  
Sampling Method: Probability Sample

### Study Population

300 patients in 80 sites (approx. 40 hospitals and 40 outpatient practices) in Germany. Each site should enrol 2-30 patients

### Criteria

Inclusion Criteria:

- Signed written informed consent prior to or at day 1 of olaparib treatment
- Women aged  $\geq 18$  years
- 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  $\geq 6$  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.
- 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))
- Patients should be in line with the specifications mentioned in the German LYNPARZA (olaparib) SmPC (Summary Product Characteristics)

Exclusion Criteria:

- Known hypersensitivity to olaparib or any of the excipients of the drug
- Patients who have started olaparib monotherapy for more than 14 days before giving their informed consent
- Pregnancy or breast feeding

## ► 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: NCT02503436

### Contacts

Contact: AstraZeneca Clinical Study Information Center 1-877-240-9479 [information.center@astrazeneca.com](mailto:information.center@astrazeneca.com)

 [Show 61 Study Locations](#)

### Sponsors and Collaborators

AstraZeneca

## ► More Information

Responsible Party: AstraZeneca  
ClinicalTrials.gov Identifier: [NCT02503436](#) [History of Changes](#)  
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Study First Received: July 8, 2015  
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Health Authority: Germany: Federal Institute for Drugs and Medical Devices

Keywords provided by AstraZeneca:

Ovarian Cancer, Fallopian Tube Cancer, primary peritoneal cancer,  
BRCA1 Gene, BRCA2 Gene

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on June 09, 2016