

A Phase III Randomised, Double Blind, Placebo Controlled, Multicentre Study of Olaparib Maintenance Monotherapy in Platinum Sensitive Relapsed BRCA Mutated Ovarian Cancer Patients who are in Complete or Partial Response Following Platinum based Chemotherapy

Published: 06-06-2013

Last updated: 22-04-2024

To determine the efficacy of olaparib versus placebo on progression free survival (PFS).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON40551

Source

ToetsingOnline

Brief title

SOLO2

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym

Ovarian Cancer

Research involving

Human

Sponsors and support

Primary sponsor: Astra Zeneca

Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: BRCA, maintenance therapy, Olaparib, Ovarian Cancer

Outcome measures

Primary outcome

Progression Free Survival

Secondary outcome

1. To determine the efficacy of olaparib maintenance monotherapy compared to placebo in BRCA mutated relapsed ovarian cancer patients who are in complete or partial response following platinum based chemotherapy by assessment of overall survival (OS), time to earliest progression by RECIST or Cancer Antigen-125 (CA-125), or death, and time from randomisation to second progression (PFS2).
2. To compare the effects of olaparib maintenance monotherapy compared to placebo on the rate of deterioration of Health-related Quality of Life (HRQoL) as assessed by the trial outcome index (TOI) of the Functional Assessment of Cancer Therapy -Ovarian (FACT-O) in BRCA mutated relapsed ovarian cancer patients who are in complete or partial response following platinum based chemotherapy.
3. To assess efficacy of olaparib in patients identified as having a deleterious or suspected deleterious variant in either of the BRCA genes using variants identified with current and future BRCA mutation assays (gene

sequencing and large rearrangement analysis).

4. To determine the exposure to olaparib in patients receiving olaparib maintenance monotherapy

5. Time from randomisation to first subsequent therapy or death (TFST), or time from randomisation to second subsequent therapy or death (TSST) or time from randomisation to study treatment discontinuation or death (TDT).

Safety:

To assess the safety and tolerability of olaparib maintenance monotherapy in BRCA mutated relapsed ovarian cancer patients

Study description

Background summary

Ovarian cancer is the fifth most common cause of death from cancer in women. The incidence of ovarian cancer increases with age and is most prevalent in the eighth decade of life. More than 70% of the patients are diagnosed with advanced disease and less than 40% of women with ovarian cancer are cured. The standard therapy for advanced ovarian cancer consists of radical debulking surgery followed by post-operative platinum-based first-line chemotherapy. Olaparib (AZD2281, KU-0059436) is a potent Polyadenosine 5'diphosphoribose [poly (ADP ribose)] polymerisation (PARP) inhibitor (PARP-1, -2 and -3). PARP enzymes are essential for repairing DNA. Olaparib can stop or block de PARP activity. Tumors with HR deficiencies (HRD), such as ovarian cancers in patients with BRCA1/2 mutations, cannot accurately repair the DNA damage, which may become lethal to cells as it accumulates. In such tumour types, olaparib may offer a potentially efficacious and less toxic cancer treatment compared with currently available chemotherapy regimens. This Phase III study will determine the efficacy by progression free survival (PFS) (using blinded independent central review (BICR) according to modified Response Evaluation Criteria In Solid Tumours (RECIST) 1.1) of olaparib maintenance monotherapy compared to placebo in BRCA mutated relapsed ovarian cancer patients who are in complete or partial response following platinum based chemotherapy.

Study objective

To determine the efficacy of olaparib versus placebo on progression free survival (PFS).

Study design

Phase 3, randomised, double-blind, placebo controlled study
Randomisation 2:1 with:
Olaparib 300 mg twice daily
Placebo twice daily

Intervention

Treatment with Olaparib 300 mg or Placebo.

Study burden and risks

Patient will get a CT scan or MRI scan every 12 weeks (RECIST). assessments will be done on a regular base, like physical examination, vital signs, blood sampling, ECGs. Pregnancy or breastfeeding is not allowed.

The risks associated with the use of olaparib are:

Anemia, neutropenia, lymphopenia, thrombocytopenia, heartburn, nausea, dizziness, diarrhea, vomiting and fatigue.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Patients must be ≥ 18 years of age. ;
- Female patients with histologically diagnosed relapsed high grade serous ovarian cancer (including primary peritoneal and / or fallopian tube cancer) or high grade endometrioid cancer.;
- Documented mutation in BRCA1 or BRCA2 that is predicted to be deleterious or suspected deleterious (known or predicted to be detrimental/lead to loss of function).;
- Patients who have received at least 2 previous lines of platinum containing therapy prior to randomisation ;
- Patients must be, in the opinion of the investigator, in response (partial or complete radiological response), or may have no evidence of disease (if optimal cytoreductive surgery was conducted prior to chemotherapy), and no evidence of a rising CA-125, following completion of this chemotherapy course;
- Patient must have received a platinum based chemotherapy regimen (e.g. carboplatin or cisplatin) and have received at least 4 cycles of treatment

Exclusion criteria

- Involvement in the planning and/or conduct of the study (applies to;both AstraZeneca staff and/or staff at the study site).;
- Patients who have had drainage of their ascites during the final 2 cycles of their last chemotherapy regimen prior to enrolment on the study.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-11-2013
Enrollment:	16
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Nog niet bekend
Generic name:	Olaparib

Ethics review

Approved WMO	
Date:	06-06-2013
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO	
Date:	12-09-2013
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO	
Date:	24-02-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO	
Date:	27-02-2014
Application type:	Amendment

Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	20-06-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	24-10-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	17-11-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	15-04-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	22-04-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	04-05-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	20-05-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	

Date:	27-06-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	13-04-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	14-04-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	14-09-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	28-09-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	26-02-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Not approved	
Date:	23-03-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	18-04-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van

Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO

Date: 26-04-2018

Application type: Amendment

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO

Date: 23-08-2018

Application type: Amendment

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO

Date: 18-09-2018

Application type: Amendment

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO

Date: 25-02-2019

Application type: Amendment

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO

Date: 15-03-2019

Application type: Amendment

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO

Date: 27-05-2019

Application type: Amendment

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO

Date: 13-06-2019

Application type: Amendment

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2013-001211-75-NL
ClinicalTrials.gov	NCT01874353
CCMO	NL45018.031.13