A Phase III, Randomised, Double Blind, Placebo Controlled, Multicentre Study of Olaparib Maintenance Monotherapy in Patients with BRCA Mutated Advanced (FIGO Stage III-IV) Ovarian Cancer following First Line Platinum Based Chemotherapy.

Published: 05-06-2013
Last updated: 19-09-2024

This study has been transitioned to CTIS with ID 2024-511142-39-00 check the CTIS register for the current data. 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-OMON54500

Source
ToetsingOnline

Brief title
SOLO1

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. 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. 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 ABR:

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 potential future BRCA mutation assays (gene sequencing and large rearrangement analysis)

4. 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).

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. 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 investigate the efficacy of olaparib administered as maintenance therapy in the first line setting for the treatment of newly diagnosed high risk advanced BRCA mutation positive ovarian cancer.

Study objective

This study has been transitioned to CTIS with ID 2024-511142-39-00 check the CTIS register for the current data.

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 (RECICT). assessments will be done on a regular base, like physical examination, vital signs, blood sampling, ECGs and questionnaires.

Pregnancy or breastfeeding is not allowed.
The risks associated with the use of olaparib are:
Anemia, neutropenea, lymphopenia, thrombocytopenie, heartburn, nausea, dizziness, diarrhea, vomiting and fatigue.

Contacts

Public
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Scientific
Astra Zeneca

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

•Female patients with newly diagnosed, histologically confirmed, high risk advanced (FIGO stage III - IV) BRCA mutated high grade serous or high grade endometriod ovarian cancer, primary peritoneal cancer and / or fallopian-tube cancer who have completed first line platinum based chemotherapy (intravenous or intraperitoneal)., • Stage III patients must have had one attempt at optimal debulking surgery (upfront or interval debulking). Stage IV patients must have

had either a biopsy and/or upfront or interval debulking surgery., • 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).

Exclusion criteria

• Patients with early stage disease (FIGO Stage I, IIA, IIB or IIC), •Stable disease or progressive disease on the post-treatment scan or clinical evidence of progression at the end of the patient's first line chemotherapy treatment., • Patients where more than one debulking surgery has been peformed before randomisation to the study. , • Patients who have previously been diagnosed and treated for earlier stage ovarian, fallopian tube or primary peritoneal cancer.

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):	12-12-2013
Enrollment:	12
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	05-06-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	12-09-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	24-02-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-02-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-06-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-08-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-02-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-02-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-04-2016

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-04-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-04-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-04-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-05-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-04-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-04-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-09-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-09-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-02-2018

Application type:	Amendment
Review commission:	METC NedMec
Not approved Date:	23-03-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-04-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-04-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-08-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-09-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-02-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-06-2019

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-04-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-09-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-09-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-03-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-03-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-12-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-01-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-03-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-04-2022

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-11-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-11-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-04-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-05-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-05-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-12-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-01-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EU-CTR	CTIS2024-511142-39-00
EudraCT	EUCTR2013-001551-13-NL
ClinicalTrials.gov	NCT01844986
CCMO	NL44290.031.13