This is a phase III randomised, double-blind, placebo-controlled, multicentre, global study to assess the effectiveness and safety of standard of care (SoC) platinum-based chemotherapy and bevacizumab followed by maintenance therapy of bevacizumab either alone, or in combination with durvalumab, or in combination with durvalumab and olaparib in patients newly diagnosed with advanced ovarian cancer.

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Mujeres	Fase III	582
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador

2022-502747-35-00 (CTIS)

Cod. Protocolo

DUO-O/D081RC00001

Transicionado 2017-004632-11

Área terapéutica

Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada

Newly diagnosed advanced (FIGO stage III-IV) high grade epithelial ovarian, fallopian or primary peritoneal cancer

Título Científico

A Phase III Randomised, Double-Blind, Placebo-Controlled, Multicentre Study of Durvalumab in Combination with Chemotherapy and Bevacizumab, Followed by Maintenance Durvalumab, Bevacizumab and Olaparib in Newly Diagnosed Advanced Ovarian Cancer Patients (DUO-O).

Justificación

No aportado

Objetivo Principal

To determine the efficacy of durvalumab and olaparib assessed by PFS in the first line treatment of non-tBRCAm HRD positive patients and all non-tBRCAm patients with newly diagnosed advanced ovarian cancer.

Variables de Evaluación Primaria

Progression Free Survival (PFS) is defined as the time from randomisation to the date of objective disease progression or death (by any cause in the absence of progression) regardless of whether the patient withdraws from assigned therapy or receives another anticancer therapy prior to progression.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

PFS in non-tBRCAm cohort
OS in non-tBRCAm HRD positive and all non-tBRCAm cohort
ORR, ORR pre-surgery in IDS group, duration of response, PFS2, TFST, TSST and TDT in non-tBRCAm cohort
Health-related Quality of Life Outcomes (HRQoL), global health status and ovarian cancer symptoms in non-tBRCAm cohort
pCR in patients undergoing IDS in non-tBRCAm cohort
PK and Ig of durvalumab in sampling of population
PK of olaparib in sampling of population
The potential additional clinical benefit in tBRCAm cohort (PFS, PFS2, ORR, ORR pre-surgery in IDS group, duration of response, TFST, TSST, TDT, HRQoL, proportion of patients with pCR in patients undergoing IDS)

Variables de Evaluación Secundaria

Progression Free Survival (PFS)
Overall Survival (OS)
Second Progression (PFS2)
Objective Response Rate (ORR)
Duration of response (DoR)

Time to first subsequent therapy (TFST)
Time to second subsequent therapy (TSST)
Time to discontinuation or death (TDT)
Pathological complete response (pCR)
Health related Quality of Life (HRQoL)
Pharmacokinetic and Immunogenicity

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Female patients with newly diagnosed, histologically confirmed, advanced (Stage III-IV) high grade epithelial ovarian cancer including high grade serous, high grade endometriod, clear cell ovarian cancer or carcinosarcoma, primary peritoneal cancer and / or fallopian-tube cancer
Patients must be aged 18 years of age
All patients should be candidates for cytoreductive surgery either: upfront primary surgery OR plan to undergo chemotherapy with interval debulking surgery
Mandatory provision of tumour sample for centralised tBRCA testing
Evidence of presence or absence of BRCA1/2 mutation in tumour tissue
ECOG performance status 0-1
Patients must have preserved organ and bone marrow function
Postmenopausal or evidence of non-childbearing status for women of childbearing potential: negative urine or serum pregnancy test

Criterios de Exclusión

Non-epithelial ovarian cancer, borderline tumors, low grade epithelial tumors or mucinous histology
Prior systemic anti-cancer therapy for ovarian cancer
Prior treatment with PARP inhibitor or immune mediated therapy
Planned intraperitoneal cytotoxic chemotherapy
Active or prior documented autoimmune or inflammatory disorders
Patients considered a poor medical risk due to a serious, uncontrolled intercurrent illness
Clinically significant cardiovascular disease
History of another primary malignancy except for - Malignancy treated with curative intent and with no known active disease 5 years before the first dose of study treatment and of low potential risk for recurrence (patients who have received prior adjuvant chemotherapy for early stage breast cancer may be eligible, provided that it was completed 3 years prior to registration, and that the patient remains free of recurrent or metastatic disease) - Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease - Adequately treated carcinoma in situ without evidence of disease - Endometrial cancer FIGO Stage IA, Grade 1 or Grade 2

Calendario

(Última actualización: 19/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
04/02/2019	22/03/2019	25/03/2019	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
09/04/2021	No aportado	No aportado	15/12/2025	No aportado

Promotor

AstraZeneca AB Sweden

Astraallen GartunaKarlebyhus Byggnad 674

Contact Person

AstraZeneca Clinical Study Information Center

+18772409479

information.center@astrazeneca.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

ceic@h12o.es

917792613

Centros

Activo (05/04/2019)

CENTRO ONCOLÓGICO MD ANDERSON INTERNATIONAL ESPAÑA

Madrid

MADRID

Oncología Médica

No iniciado (--/--/----)

Fundacio Assistencial De Mutua De Terrassa Fpc

Terrassa

BARCELONA

Oncology Department

Activo (22/03/2019)

HOSPITAL CLÍNICO SAN CARLOS

Madrid

MADRID

Oncología Médica

Activo (29/03/2019)

HOSPITAL GENERAL, MATERNO E INFANTIL REINA SOFÍA

Córdoba

CÓRDOBA

Oncología Médica

Activo (28/03/2019)

HOSPITAL RAMÓN Y CAJAL

Madrid

MADRID

Oncología Médica

Activo (29/03/2019)

HOSPITAL UNIVERSITARI MÚTUA DE TERRASSA

Terrassa

BARCELONA

Oncología Médica

Cerrado (11/10/2019)

HOSPITAL UNIVERSITARIO DE GRAN CANARIA DR. NEGRÍN

Palmas de Gran Canaria, Las

LAS PALMAS

Oncología Médica

Activo (22/03/2019)

HOSPITAL UNIVERSITARIO ALVARO CUNQUEIRO

Vigo

PONTEVEDRA

Oncología Médica

Activo (28/03/2019)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Oncología Médica

Medicamentos

MYCOPHENOLATE MOFETIL
CAPSULES
ORAL

-

Principios Activos: N/A

Experimental

INFLIXIMAB
POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Principios Activos: N/A

Experimental

IMFINZI 50 mg/mL concentrate for solution for infusion.
SOLUTION FOR INFUSION
INTRAVENOUS USE

Código ATC: L01FF03 - DURVALUMAB
Principios Activos: N/A

Experimental

Lynparza 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX46 - OLAPARIB
Principios Activos: N/A

Experimental

Lynparza 150 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX46 - OLAPARIB
Principios Activos: N/A

Experimental

BEVACIZUMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Principios Activos: N/A

Experimental

Sin resultados

This is a phase III randomised, double-blind, placebo-controlled, multicentre, global study to assess the effectiveness and safety of standard of care (SoC) platinum-based chemotherapy and bevacizumab followed by maintenance therapy of bevacizumab either alone, or in combination with durvalumab, or in combination with durvalumab and olaparib in patients newly diagnosed with advanced ovarian cancer.

State	Type of participants	Age Ranges
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Women	Phase III	582
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2022-502747-35-00 (CTIS)

Protocol Code
DUO-O/D081RC00001

Transitioned 2017-004632-11

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Newly diagnosed advanced (FIGO stage III-IV) high grade epithelial ovarian, fallopian or primary peritoneal cancer

Scientific Title

A Phase III Randomised, Double-Blind, Placebo-Controlled, Multicentre Study of Durvalumab in Combination with Chemotherapy and Bevacizumab, Followed by Maintenance Durvalumab, Bevacizumab and Olaparib in Newly Diagnosed Advanced Ovarian Cancer Patients (DUO-O).

Rationale

Not provided

Main Objective

To determine the efficacy of durvalumab and olaparib assessed by PFS in the first line treatment of non-tBRCAm HRD positive patients and all non-tBRCAm patients with newly diagnosed advanced ovarian cancer.

Primary Endpoints

Progression Free Survival (PFS) is defined as the time from randomisation to the date of objective disease progression or death (by any cause in the absence of progression) regardless of whether the patient withdraws from assigned therapy or receives another anticancer therapy prior to progression.

Temporary moments of secondary assessment

Not provided

Secondary Objective

PFS in non-tBRCAm cohort
OS in non-tBRCAm HRD positive and all non-tBRCAm cohort
ORR, ORR pre-surgery in IDS group, duration of response, PFS2, TFST, TSST and TDT in non-tBRCAm cohort
Health-related Quality of Life Outcomes (HRQoL), global health status and ovarian cancer symptoms in non-tBRCAm cohort
pCR in patients undergoing IDS in non-tBRCAm cohort
PK and Ig of durvalumab in sampling of population
PK of olaparib in sampling of population
The potential additional clinical benefit in tBRCAm cohort (PFS, PFS2, ORR, ORR pre-surgery in IDS group, duration of response, TFST, TSST, TDT, HRQoL, proportion of patients with pCR in patients undergoing IDS)

Secondary Endpoints

Progression Free Survival (PFS)
Overall Survival (OS)
Second Progression (PFS2)
Objective Response Rate (ORR)
Duration of response (DoR)

Time to first subsequent therapy (TFST)
Time to second subsequent therapy (TSST)
Time to discontinuation or death (TDT)
Pathological complete response (pCR)
Health related Quality of Life (HRQoL)
Pharmacokinetic and Immunogenicity

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Female patients with newly diagnosed, histologically confirmed, advanced (Stage III-IV) high grade epithelial ovarian cancer including high grade serous, high grade endometriod, clear cell ovarian cancer or carcinosarcoma, primary peritoneal cancer and / or fallopian-tube cancer
Patients must be aged 18 years of age
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Patients must have preserved organ and bone marrow function
Postmenopausal or evidence of non-childbearing status for women of childbearing potential: negative urine or serum pregnancy test

Exclusion criteria

Non-epithelial ovarian cancer, borderline tumors, low grade epithelial tumors or mucinous histology
Prior systemic anti-cancer therapy for ovarian cancer
Prior treatment with PARP inhibitor or immune mediated therapy
Planned intraperitoneal cytotoxic chemotherapy
Active or prior documented autoimmune or inflammatory disorders
Patients considered a poor medical risk due to a serious, uncontrolled intercurrent illness
Clinically significant cardiovascular disease
History of another primary malignancy except for - Malignancy treated with curative intent and with no known active disease 5 years before the first dose of study treatment and of low potential risk for recurrence (patients who have received prior adjuvant chemotherapy for early stage breast cancer may be eligible, provided that it was completed 3 years prior to registration, and that the patient remains free of recurrent or metastatic disease) - Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease - Adequately treated carcinoma in situ without evidence of disease - Endometrial cancer FIGO Stage IA, Grade 1 or Grade 2

Calendar

(Last Update: 19/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
04/02/2019	22/03/2019	25/03/2019	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
09/04/2021	Not aported	Not aported	15/12/2025	Not aported

Sponsor

AstraZeneca AB Sweden

Astraallen GartunaKarlebyhus Byggnad 674

Contact Person

AstraZeneca Clinical Study Information Center

+18772409479

information.center@astrazeneca.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

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Sites

Active (05/04/2019)

CENTRO ONCOLÓGICO MD ANDERSON INTERNATIONAL ESPAÑA

Madrid

MADRID

Oncología Médica

not initialized (--/--/----)

Fundacio Assistencial De Mutua De Terrassa Fpc

Terrassa

BARCELONA

Oncology Department

Active (22/03/2019)

HOSPITAL CLÍNICO SAN CARLOS

Madrid

MADRID

Oncología Médica

Active (29/03/2019)

HOSPITAL GENERAL, MATERNO E INFANTIL REINA SOFÍA

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Active (28/03/2019)

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Madrid

MADRID

Oncología Médica

Active (29/03/2019)

HOSPITAL UNIVERSITARI MÚTUA DE TERRASSA

Terrassa

BARCELONA

Oncología Médica

Closed (11/10/2019)

HOSPITAL UNIVERSITARIO DE GRAN CANARIA DR. NEGRÍN

Palmas de Gran Canaria, Las

LAS PALMAS

Oncología Médica

Active (22/03/2019)

HOSPITAL UNIVERSITARIO ALVARO CUNQUEIRO

Vigo

PONTEVEDRA

Oncología Médica

Active (28/03/2019)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Oncología Médica

Medication

MYCOPHENOLATE MOFETIL
CAPSULES
ORAL

-

Active Principles: N/A

Experimental

INFLIXIMAB
POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

IMFINZI 50 mg/mL concentrate for solution for infusion.
SOLUTION FOR INFUSION
INTRAVENOUS USE

ATC code: L01FF03 - DURVALUMAB

Active Principles: N/A

Experimental

Lynparza 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01XX46 - OLAPARIB

Active Principles: N/A

Experimental

Lynparza 150 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01XX46 - OLAPARIB

Active Principles: N/A

Experimental

BEVACIZUMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

No results