

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
EC Finalizado

Tipo de Participantes
No aportado

Rangos de Edad
Mayores de 64 , Adultos (18-64 años)

Género
Mujeres

Fases
Fase III

Participantes esperados
582

Resultados
Sin resultados

Bajo nivel intervención
No

Enfermedad rara
No

Cobertura geográfica
Sin determinar

Ámbitos del ensayo
seguridad, eficacia

Terapia avanzada
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-tBRCa HRD positive patients and all non-tBRCa 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-tBRCa cohort
OS in non-tBRCa HRD positive and all non-tBRCa cohort
ORR, ORR pre-surgery in IDS group, duration of response, PFS2, TFST, TSST and TDT in non-tBRCa cohort
Health-related Quality of Life Outcomes (HRQoL), global health status and ovarian cancer symptoms in non-tBRCa cohort
pCR in patients undergoing IDS in non-tBRCa cohort
PK and Ig of durvalumab in sampling of population
PK of olaparib in sampling of population
The potential additional clinical benefit in tBRCa 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 endometrioid, 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 04/02/2019	Inicio de Ensayo 22/03/2019	Inclusión Primer Paciente 25/03/2019	Interrumpido No aportado	Reiniciado No aportado
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Fin de reclutamiento 09/04/2021	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España 15/12/2025	Fin del ensayo global No aportado
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Promotor

AstraZeneca AB Sweden

Astraallen GartunaKarlebyhus Byggnad 674

Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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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
Finished CT

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Women

Phases
Phase III

Expected Participants
582

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness

Advanced therapy
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
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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 endometrioid, clear cell ovarian cancer or carcinosarcoma, primary peritoneal cancer and / or fallopian-tube cancer
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Exclusion criteria

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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 04/02/2019	Start of Trial 22/03/2019	First patient inclusion 25/03/2019	Halted Not aported	Restarted Not aported
End of recruitment 09/04/2021	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) 15/12/2025	Trial end (Global) Not aported

Sponsor

AstraZeneca AB Sweden

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Contact Person

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Monetary support: N/A

Sponsor type: Commercial

Ceim

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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
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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

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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