

Trial record 1 of 1 for: YO39523

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A Study of Atezolizumab Versus Placebo in Combination With Paclitaxel, Carboplatin, and Bevacizumab in Participants With Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (IMagyn050)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. **▲** [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier:
NCT03038100

[Recruitment Status](#) ⓘ: Recruiting
[First Posted](#) ⓘ: January 31, 2017
[Last Update Posted](#) ⓘ: June 19, 2018

See [Contacts and Locations](#)

Sponsor:

Hoffmann-La Roche

Collaborators:

GOG Foundation

European Network of Gynaecological Oncological Trial Groups (ENGOT)

Information provided by (Responsible Party):

Hoffmann-La Roche

[Study Details](#)
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[How to Read a Study Record](#)

Study Description

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Brief Summary:

This is a Phase III, global, double-blind, 2-arm randomized study designed to compare the efficacy and safety of atezolizumab + paclitaxel + carboplatin + bevacizumab versus placebo + paclitaxel + carboplatin + bevacizumab. Study participants will have Stage 3 or 4 ovarian cancer (OC), fallopian tube cancer (FTC), or primary peritoneal cancer (PPC) with macroscopic residual disease postoperatively (i.e., after primary tumor reductive surgery) or who will undergo neoadjuvant therapy followed by interval surgery.

Condition or disease ⓘ	Intervention/treatment ⓘ	Phase ⓘ
Ovarian Cancer	Drug: Paclitaxel	Phase 3
Fallopian Tube Cancer	Drug: Carboplatin	

Peritoneal Neoplasms	Drug: Atezolizumab
	Drug: Bevacizumab
	Drug: Atezolizumab Placebo

Study Design

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Study Type ⓘ: Interventional (Clinical Trial)
Estimated Enrollment ⓘ: 1300 participants
Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double (Participant, Investigator)
Primary Purpose: Treatment
Official Title: A Phase III, Multicenter, Randomized, Study of Atezolizumab Versus Placebo Administered in Combination With Paclitaxel, Carboplatin, and Bevacizumab to Patients With Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
Actual Study Start Date ⓘ: March 8, 2017
Estimated Primary Completion Date ⓘ: April 1, 2020
Estimated Study Completion Date ⓘ: December 1, 2021

Resource links provided by the National Library of Medicine



[Genetics Home Reference](#) related topics:

[Ovarian cancer](#)

[Drug Information](#) available for: [Paclitaxel](#) [Carboplatin](#)

[Bevacizumab](#) [Atezolizumab](#)

[Genetic and Rare Diseases Information Center](#) resources:

[Ovarian Cancer](#) [Ovarian Epithelial Cancer](#)

[Fallopian Tube Cancer](#)

[U.S. FDA Resources](#)

Arms and Interventions

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Arm ⓘ	Intervention/treatment ⓘ
<p>Experimental: Atezolizumab With Paclitaxel, Carboplatin and Bevacizumab</p> <p>Participants in the primary tumor-reductive surgery group will receive paclitaxel, carboplatin, atezolizumab intravenous (IV) infusion on Day 1 of each 21-day cycle for a total of 6 cycles, and bevacizumab IV infusion starting with Cycle 2 for a total of 5 cycles, followed by maintenance therapy bevacizumab with atezolizumab for a total of 22 cycles of atezolizumab and 21 cycles of bevacizumab. Participants in the neoadjuvant therapy group will receive paclitaxel, carboplatin and atezolizumab for 6 cycles and bevacizumab for 4 cycles. Interval surgery will occur between cycles 3 and 4. Each cycle is 21 days long. After 6 cycles, participants will start maintenance therapy of bevacizumab and atezolizumab for additional 16 cycles.</p>	<p>Drug: Paclitaxel</p> <p>Paclitaxel 175 milligrams per square meter (mg/m²) IV infusion on Day 1 of each 21-day cycle</p> <p>Drug: Carboplatin</p> <p>Carboplatin at a dose to achieve a target area under the curve (AUC) of 6 milligrams per milliliter*minute (mg/mL*min) on Day 1 of each</p>

	<p>21-day cycle for a total of 6 cycles</p> <p>Drug: Atezolizumab Atezolizumab 1200 mg IV infusion on Day 1 of each 21-day cycle</p> <p>Drug: Bevacizumab Bevacizumab 15 milligrams per kilogram (mg/kg) IV infusion as per the schedule specified in respective arms</p>
<p>Placebo Comparator: Placebo With Paclitaxel, Carboplatin and Bevacizumab</p> <p>Participants in the primary tumor-reductive surgery group will receive paclitaxel, carboplatin, atezolizumab placebo IV infusion on Day 1 of each 21-day cycle for a total of 6 cycles, and bevacizumab IV infusion starting with Cycle 2 for a total of 5 cycles, followed by maintenance therapy bevacizumab with atezolizumab placebo for a total of 22 cycles of atezolizumab placebo and 21 cycles of bevacizumab. Participants in the neoadjuvant therapy group will receive paclitaxel, carboplatin and placebo for 6 cycles and bevacizumab for 4 cycles. Interval surgery will occur between cycles 3 and 4. Each cycle is 21 days long. After 6 cycles, participants will start maintenance therapy of bevacizumab and placebo for additional 16 cycles.</p>	<p>Drug: Paclitaxel Paclitaxel 175 milligrams per square meter (mg/m²) IV infusion on Day 1 of each 21-day cycle</p> <p>Drug: Carboplatin Carboplatin at a dose to achieve a target area under the curve (AUC) of 6 milligrams per milliliter*minute (mg/mL*min) on Day 1 of each 21-day cycle for a total of 6 cycles</p> <p>Drug: Bevacizumab Bevacizumab 15 milligrams per kilogram (mg/kg) IV infusion as per the schedule specified in respective arms</p> <p>Drug: Atezolizumab Placebo Placebo matching to atezolizumab on Day 1 of each 21-day cycle</p>

Outcome Measures

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Primary Outcome Measures

1. Progression-Free Survival (PFS) Assessed by Investigator as Per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) - Intent-to-Treat (ITT) Population [Time Frame: From randomization until disease progression or death from any cause (up to approximately 55 months)]
2. PFS Assessed by Investigator as Per RECIST v1.1 - Programmed Death-Ligand 1 (PD-L1)-Positive

- Subpopulation [Time Frame: From randomization until disease progression or death from any cause (up to approximately 55 months)]
3. Overall Survival - ITT Population [Time Frame: From randomization up to death from any cause (up to approximately 60 months)]
 4. Overall Survival - PD-L1–Positive Subpopulation [Time Frame: From randomization up to death from any cause (up to approximately 60 months)]

Secondary Outcome Measures ⓘ:

1. Percentage of Participants With Objective Response (OR) Assessed by Investigator as Per RECIST v1.1 - Primary Tumor-Reductive Surgery (Having Residual Measurable Disease) Group [Time Frame: From randomization until disease progression or death from any cause (up to approximately 55 months)]
2. Duration of Response Assessed by Investigator as Per RECIST v1.1 - Primary Tumor-Reductive Surgery (Having Residual Measurable Disease) Group [Time Frame: From the date of first occurrence of a confirmed complete or partial response until disease progression or death from any cause (up to approximately 55 months)]
3. Percentage of Participants who Achieve a Clinically-Meaningful Improvement in Patient-Reported Abdominal Pain or Bloating - Neoadjuvant Group [Time Frame: From randomization to the end of treatment/discontinuation (up to approximately 70 weeks), and during follow-up period (up to approximately 60 months)]

Clinically-meaningful improvement in patient-reported abdominal pain or bloating will be assessed using European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaires Ovarian Cancer Module 28 (EORTC QLQ-OV28) Abdominal/Gastrointestinal Symptom Scale (Items 31 and 31).

4. Percentage of Participants who Achieve a Clinically-Meaningful Improvement in Patient-Reported Function and Health Related Quality of Life (HRQoL) - Neoadjuvant Group [Time Frame: From randomization to the end of treatment/discontinuation (up to approximately 70 weeks), and during follow-up period (up to approximately 60 months)]

Clinically-meaningful improvement in patient-reported function and HRQoL will be assessed using European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaires Core 30 (EORTC QLQ-C30).

5. Percentage of Participants who Achieve a Clinically-Meaningful Improvement, Remain Stable or Deterioration in Patient-Reported Function and HRQoL - Primary Tumor-Reductive Surgery Group [Time Frame: From randomization to the end of treatment/discontinuation (up to approximately 66 weeks), and during follow-up period (up to approximately 60 months)]

Clinically-meaningful improvement in patient-reported function and HRQoL will be assessed using EORTC QLQ-C30.

6. Percentage of Participants With Adverse Events [Time Frame: From randomization up to 90 days after last dose of study treatment or until initiation of new anti-cancer therapy (up to approximately 82 weeks)]
7. Maximum Serum Concentration (C_{max}) of Atezolizumab [Time Frame: Pre-infusion (0 hour [hr]), 30 minutes (min) after end of infusion (EOI) on Cycle 1 Day 1(Cycle length=21 days) up to approximately 82 weeks (detailed timeframe is provided in outcome measure description)]

Primary surgery group: Pre-infusion (0 hr), 30 min after EOI (infusion duration=60 min) on Day 1 of Cycles 1 and 3; pre-infusion (0 hr) on Day 1 of Cycles 2, 4, 8, 16 (each cycle=21 days); end of treatment/discontinuation visit (up to approximately 66 weeks); \geq 90 days after last dose (up to approximately 78 weeks) Neoadjuvant therapy group: Pre-infusion (0 hr), 30 min after EOI (infusion

duration=60 min) on Day 1 of Cycles 1 and 3; pre-infusion (0 hr) on Day 1 of Cycles 2, 4 (each cycle=21 days); end of treatment/discontinuation visit (up to approximately 70 weeks); \geq 90 days after last dose (up to approximately 82 weeks)

8. Minimum Serum Concentration (Cmin) of Atezolizumab [Time Frame: Pre-infusion (0 hr), 30 min after EOI on Cycle 1 Day 1(Cycle length=21 days) up to approximately 82 weeks (detailed timeframe is provided in outcome measure description)]

Primary surgery group: Pre-infusion (0 hr), 30 min after EOI (infusion duration=60 min) on Day 1 of Cycles 1 and 3; pre-infusion (0 hr) on Day 1 of Cycles 2, 4, 8, 16 (each cycle=21 days); end of treatment/discontinuation visit (up to approximately 66 weeks); \geq 90 days after last dose (up to approximately 78 weeks) Neoadjuvant therapy group: Pre-infusion (0 hr), 30 min after EOI (infusion duration=60 min) on Day 1 of Cycles 1 and 3; pre-infusion (0 hr) on Day 1 of Cycles 2, 4 (each cycle=21 days); end of treatment/discontinuation visit (up to approximately 70 weeks); \geq 90 days after last dose (up to approximately 82 weeks)

9. Percentage of Participants With Anti-Drug Antibodies (ADAs) to Atezolizumab [Time Frame: Pre-infusion (0 hr) on Cycle 1 Day 1(Cycle length=21 days) up to approximately 82 weeks (detailed timeframe is provided in outcome measure description)]

Primary surgery group: Pre-infusion (0 hr) on Day 1 of Cycles 1, 2, 3, 4, 8, 16 (each cycle=21 days); end of treatment/discontinuation visit (up to approximately 66 weeks); \geq 90 days after last dose (up to approximately 78 weeks) Neoadjuvant therapy group: Pre-infusion (0 hr) on Day 1 of Cycles 1, 2, 3, 4 (each cycle=21 days); end of treatment/discontinuation visit (up to approximately 70 weeks); \geq 90 days after last dose (up to approximately 82 weeks)

Eligibility Criteria

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Information from the National Library of Medicine



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, [Learn About Clinical Studies](#).

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: Female

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Participants receiving a histologic diagnosis of epithelial ovarian cancer (EOC), peritoneal primary carcinoma, or fallopian tube cancer
- Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2
- Life expectancy greater than ($>$) 12 weeks
- For participants who receive therapeutic anticoagulation: stable anticoagulant regimen

- Availability of a representative formalin-fixed, paraffin-embedded (FFPE) tumor specimen in paraffin blocks (preferred) or at least 20 unstained slides (for detailed tissue requirements at screening)

Exclusion Criteria:

- Received a current diagnosis of borderline epithelial ovarian tumor (formerly tumors of low malignant potential)
- Have recurrent invasive epithelial ovarian, fallopian tube, or primary peritoneal cancer that was treated only with surgery (example [e.g.], participants with Stage IA or Stage IB epithelial ovarian or fallopian tube cancers)
- Have non-epithelial ovarian tumors (e.g., germ cell tumors, sex cord stromal tumors)
- Received prior radiotherapy to any portion of the abdominal cavity or pelvis
- Received prior chemotherapy for any abdominal or pelvic tumor that include neoadjuvant chemotherapy (NACT) for ovarian, primary peritoneal or fallopian tube cancer
- Received any biological and/or targeted therapy (including but not limited to vaccines, antibodies, tyrosine kinase inhibitors) or hormonal therapy for management and/or treatment of epithelial ovarian or peritoneal primary cancer
- Have synchronous primary endometrial cancer
- Have a prior history of primary endometrial cancer, except: Stage IA cancer; superficial myometrial invasion, without lymphovascular invasion; grade less than (<) 3 or poorly differentiated subtypes, and this includes papillary serous, clear cell or other International Federation of Gynecological Oncologists (FIGO) Grade 3 lesions
- With the exception of non-melanoma skin cancer and other specific malignancies as noted above, other invasive malignancies with any evidence of other cancers present within the last 5 years or previous cancer treatment that contraindicates this protocol therapy
- Have a known hypersensitivity or allergy to biopharmaceutical agents produced in Chinese hamster ovary cells or any component of the atezolizumab and/or bevacizumab formulations
- Undergo major surgical procedure within 28 days prior to first bevacizumab dose, or anticipation of the need for a major surgical procedure during the course of the study except participants who receive NACT and will need interval surgery. This may include but is not limited to laparotomy.
- Have prior allogeneic bone marrow transplantation or solid organ transplant
- Have any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that may affect the interpretation of the results
- Have any approved or investigational anti-cancer therapy, including chemotherapy or hormonal therapy, with exceptions: Hormone-replacement therapy or oral contraceptives
- Are administered treatment with any other investigational agent or participation in another clinical study with anti-cancer therapeutic intent
- Have core biopsy or other minor surgical procedures within 7 days prior to the first dose of bevacizumab
- Have known sensitivity to any component of bevacizumab
- Have known sensitivity to any component of paclitaxel
- Current treatment with anti-viral therapy for hepatitis B virus (HBV)
- History of leptomenigeal disease

Contacts and Locations

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Information from the National Library of Medicine



To learn more about this study, you or your doctor may contact the study research staff

using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT03038100**

Contacts

Contact: Reference Study ID Number: **YO39523** www.roche.com/about_roche/roche_worldwide.htm 888-662-6723

[+](#) [Show 359 Study Locations](#)

Sponsors and Collaborators

Hoffmann-La Roche

GOG Foundation

European Network of Gynaecological Oncological Trial Groups (ENGOT)

Investigators

Study Director: Clinical Trials Hoffmann-La Roche

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Responsible Party: Hoffmann-La Roche
ClinicalTrials.gov Identifier: [NCT03038100](#) [History of Changes](#)
Other Study ID Numbers: **YO39523**
2016-003472-52 (EudraCT Number)
First Posted: January 31, 2017 [Key Record Dates](#)
Last Update Posted: June 19, 2018
Last Verified: June 2018

Studies a U.S. FDA-regulated Drug Product: Yes

Studies a U.S. FDA-regulated Device Product: No

Additional relevant MeSH terms:

Fallopian Tube Neoplasms	Albumin-Bound Paclitaxel
Peritoneal Neoplasms	Bevacizumab
Genital Neoplasms, Female	Carboplatin
Urogenital Neoplasms	Antibodies, Monoclonal
Neoplasms by Site	Antineoplastic Agents, Phytogenic
Neoplasms	Antineoplastic Agents
Fallopian Tube Diseases	Tubulin Modulators
Adnexal Diseases	Antimitotic Agents
Genital Diseases, Female	Mitosis Modulators
Abdominal Neoplasms	Molecular Mechanisms of Pharmacological Action
Digestive System Neoplasms	Angiogenesis Inhibitors
Digestive System Diseases	Angiogenesis Modulating Agents
Peritoneal Diseases	Growth Substances
Paclitaxel	Physiological Effects of Drugs
Atezolizumab	Growth Inhibitors