ForPatients
by Roche

Peritoneal NeoplasmsFallopian Tube CancerOvarian Cancer

A clinical trial comparing atezolizumab with a placebo when given with chemotherapy (paclitaxel and carboplatin) and bevacizumab in people newly diagnosed with advanced ovarian, fallopian tube or peritoneal cancer.

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

Trial Status	Trial Runs In	Trial Identifier
Completed	22 Countries	NCT03038100 2016-003472-52 YO39523

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

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

Trial 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.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03038100 2016-003472-52 YO39523
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

Female	#18 Years	No

How does the IMagyn050 clinical trial work?
This clinical trial is for patients who have advanced ovarian cancer, fallopian tube cancer or peritoneal cancer.

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab against placebo, when given with chemotherapy (paclitaxel and carboplatin) and bevacizumab, in patients with ovarian, fallopian tube or peritoneal cancer. If you take part in this clinical trial, you will be given either atezolizumab or a placebo, along with chemotherapy (paclitaxel and carboplatin) and bevacizumab.

How do I take part in this clinical trial?
To be able to take part in this clinical trial, you must have been recently diagnosed with advanced ovarian, fallopian tube or peritoneal cancer.

Your cancer needs to be a new cancer. Your cancer cannot be a previous cancer that has come back after treatment, including biological therapy, targeted therapy or hormone therapy. You also must not have had chemotherapy or radiation therapy for any cancers in the stomach area or pelvis. You will not be allowed to join the trial if you also have endometrial cancer.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, if you are not currently pregnant but can become pregnant, you will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?
Everyone who joins this clinical trial will be split into 2 groups depending on whether or not they have already had surgery before entering the trial:

Group 1 – treatment for patients who have already had surgery Everyone in this group will have had surgery before joining the study. During that surgery, their surgeon will have removed as much cancer as possible. The patients in this group will be split into 2 sub-groups randomly (like flipping a coin) and given either:

- Atezolizumab, chemotherapy and bevacizumab (all given as infusions into your vein every 3 weeks)
- OR placebo, chemotherapy and bevacizumab (all given as infusions into your vein every 3 weeks)

You will be given a total of 22 rounds of treatment, but not all of the treatments will be given each time:

- The first round of treatment will only include chemotherapy and atezolizumab OR placebo (you will not receive bevacizumab)
- The next 5 rounds of treatment will include all three treatments (chemotherapy, bevacizumab and atezolizumab OR placebo)
- The next 16 rounds of treatment will only include bevacizumab and atezolizumab OR placebo (you will not receive chemotherapy)

You will have a 1 in 2 chance of being placed in the group being given atezolizumab or the group being given placebo.

Group 2 – surgery after treatment has started Everyone in this group will have surgery during the study. Patients in this group will be split into 2 sub-groups randomly (like flipping a coin) and given either:

- Atezolizumab, chemotherapy and bevacizumab (all given as infusions into your vein every 3 weeks)
- OR placebo, chemotherapy and bevacizumab (all given as infusions into your vein every 3 weeks)

You will be given a total of 22 rounds of treatment, but not all of the treatments will be given each time:

- The first 2 rounds of treatment will include all three treatments (chemotherapy, bevacizumab and atezolizumab OR placebo)
- Your surgery to remove the cancer will happen after 3 rounds of treatment. The treatments just before and just after your surgery (treatment rounds 3 and 4) will only include chemotherapy and atezolizumab OR placebo (you will not receive bevacizumab)
- The next 16 rounds of treatment will only include bevacizumab and atezolizumab OR placebo (you will not receive chemotherapy)

You will have a 1 in 2 chance of being placed in the group being given atezolizumab or the group being given placebo.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given medicine with no active ingredients (also known as a ‘placebo’). A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial. All patients will be given chemotherapy and bevacizumab, which are the current standard treatments for ovarian, fallopian tube or peritoneal cancer.

Neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in, if your safety is at risk. If your cancer gets worse while you are on this trial and the doctor wants to change your treatment or put you on a different clinical trial, no one will be able to tell you whether or not you were given atezolizumab or placebo until this clinical trial is completely finished. Not having this information might mean that you are not suitable to take part in other clinical trials testing new drugs.

How often will I be seen in follow-up appointments, and for how long?
You will be given the clinical trial treatment atezolizumab OR placebo, with paclitaxel, carboplatin and bevacizumab for about 1 year and 3 months. You are free to stop this treatment at any time. After being given treatment, you will still be seen regularly by the clinical trial doctor every 3–6 months. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having. Your doctor will explain all of the hospital visits and checks to you if you would like to take part in the trial.

What happens if I am unable to take part in this clinical trial?
If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT03038100

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 leptomeningeal disease