ForPatients
by Roche

Ovarian Cancer

Platinum-based Chemotherapy With Atezolizumab and Niraparib in Patients With Recurrent Ovarian Cancer (ENGOT-Ov41 / GEICO 69-O / ANITA)

Platinum-based Chemotherapy With Atezolizumab and Niraparib in Patients With Recurrent Ovarian Cancer (ANITA)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	5 Countries	NCT03598270 2018-000366-11, ENGOT-Ov41, GEICO 69-O ENGOT-Ov41/GEICO 69-O/ANITA

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

Atezolizumab in this study is expected to have a positive benefit-risk profile for the treatment of patients with platinum-sensitive relapse of ovarian cancer. Of interest, atezolizumab is being investigated also in combination with platinum-based doublet chemotherapy in second line (2L)/ third line (3L) platinum-sensitive recurrent ovarian cancer patients in ATALANTE (NCT02891824), which also includes bevacizumab in the combination. The study is proceeding as expected after >100 patients enrolled and under independent Data Monitoring Committee (IDMC) supervision. Platinum-containing therapy is considered the treatment of choice for patients with platinum-sensitive relapse. However the duration of response and the prolongation of the progression free interval with chemotherapy are usually brief, among other because these chemotherapy regimens cannot be continued until progression as they are associated with neurological, renal and hematological toxicity and cannot generally be tolerated for more than about 6 to 9 cycles. Niraparib received FDA approval in March 2017 as maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy. Recently, the European Medicines Agency (EMA) has also approved niraparib as maintenance monotherapy. Despite the progress brought about by niraparib, there is a need for a more effective treatment to extend the progression free interval in this patient population. The combination with immune checkpoint inhibitors such as anti-death protein 1 (anti-PD1) or anti-death protein ligand 1 (anti-PD-L1) has a compelling rationale to this aim, especially under the light of the emerging clinical data of this combination. The use of atezolizumab concurrent to platinum-containing chemotherapy followed by niraparib as maintenance therapy after completion of chemotherapy, as per normal clinical practice, may provide further benefit to patients in terms of prolonging the progression free interval

and increasing the interval between lines of chemotherapy, hence delaying further hospitalization and the cumulative toxicities associated with chemotherapy. Additionally, preliminary studies with atezolizumab suggest an acceptable tolerability profile for long term clinical use in recurrent ovarian cancer patients and other indications.

Grupo Español de Investigación en Cáncer de Ovario	**Phase 3**
Sponsor	Phase

NCT03598270 2018-000366-11, ENGOT-Ov41, GEICO 69-O ENGOT-Ov41/GEICO 69-O/ANITA
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	**>=18 Years**	**No**

How does the ANITA clinical trial work?
This clinical trial is recruiting people who have ovarian, fallopian tube or peritoneal cancer. In order to take part, patients must have cancer that has come back more than 6 months after treatment with a type of chemotherapy called ‘platinum-based chemotherapy’.

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab with a placebo (when given with platinum-based chemotherapy and niraparib) in people with ovarian, tubal or peritoneal cancer. If you take part in this clinical trial, you will receive the current standard treatment of platinum-based chemotherapy followed by niraparib maintenance that you would have received as part of your regular treatment. You will also receive either the new treatment atezolizumab or a placebo. The type of chemotherapy will be decided by the clinical trial doctors and will affect how often you are seen for treatment.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must have been diagnosed with ovarian, fallopian tube or peritoneal cancer, and your cancer must have come back over 6 months after your last platinum-based chemotherapy treatment.

You must not have previously received more than two separate courses of chemotherapy and you cannot take part in the trial if you are pregnant or breastfeeding.

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 randomly (like flipping a coin):

Group 1

Everyone in Group 1 will be given:

Chemotherapy phase

- 4–6 rounds of treatment with atezolizumab and chemotherapy, both given as infusions into your vein every 3–4 weeks
- If your cancer does not get worse and your body can tolerate the treatment, you will be able to start the ‘maintenance phase’ with atezolizumab and niraparib. You must have received at least 4 rounds of chemotherapy to start the ‘maintenance phase’. Before you start niraparib, the doctors will monitor you for at least 3 weeks (but no more than 3 months) after you finish chemotherapy to check how you are responding to the treatment and if you have any toxicities

Maintenance phase

- Atezolizumab given as an infusion into your vein every 3 weeks and niraparib given as tablets to swallow every day

OR

Group 2

Everyone in Group 2 will be given:

Chemotherapy phase

- 4–6 rounds of treatment with a placebo and chemotherapy, both given as infusions into your vein every 3–4 weeks
- If your cancer does not get worse and your body can tolerate the treatment, you will be able to start the 'maintenance phase' with placebo and niraparib. You must have received at least 4 rounds of chemotherapy to start the 'maintenance phase'. Before you start niraparib, the doctors will monitor you for at least 3 weeks (but no more than 3 months) after you finish chemotherapy to check how you are responding to the treatment and if you have any toxicities

Maintenance phase

- Placebo given as an infusion into your vein every 3 weeks and niraparib as tablets to swallow every day

You will have a 1 in 2 chance of being placed in any group.

This is a 'placebo-controlled' clinical trial, which means that one of the groups will be given a medicine with no active ingredients (also known as a 'placebo') as well as the current standard treatment (chemotherapy and niraparib). A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial.

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.

How often will I be seen in follow-up appointments and for how long?
You will be given the clinical trial treatment as long as it can help you, up to a maximum of around 3 years. You are free to stop this treatment at any time. After being given treatment, you will be seen by the clinical trial doctor after 1 month and then every 3 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.

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

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