

ForPatients

by Roche

Cervical Cancer

Platinum Chemotherapy Plus Paclitaxel With Bevacizumab and Atezolizumab in Metastatic Carcinoma of the Cervix (ENGOT-Cx10 / GEICO 68-C / JGOG1084 / GOG-3030 / BEATcc)

Platinum Chemotherapy Plus Paclitaxel With Bevacizumab and Atezolizumab in Metastatic Carcinoma of the Cervix

Trial Status

Active, not recruiting

Trial Runs In

8 Countries

Trial Identifier

NCT03556839 2018-000367-83, ENGOT-Cx10, GEICO 68-C, JGOG1084, GOG-3030 ENGOT-Cx10 / BEATcc

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

Trial Summary:

The study will integrate the efficacy of combining the anti programmed death-ligand 1 (anti-PD-L1) agent atezolizumab with the current standard of care in Stage IVB , persistent or recurrent carcinoma of the cervix, namely cisplatin or carboplatin/paclitaxel/ bevacizumab. It will be explored the combination of bevacizumab plus atezolizumab, with no patient selection based on PD-L1 expression, allowing an all-comer assessment of atezolizumab activity. The study is a randomized open label phase III trial to investigate the impact of atezolizumab in combination with bevacizumab and cisplatin or carboplatin / paclitaxel chemotherapy on overall survival and will employ the intent to treat principle, and random assignment to one of the 2 arms will be balanced according to disease histology (squamous cell carcinoma vs adenocarcinoma), prior platinum therapy as a radiation sensitizer (no prior cis-Radiotherapy (RT) versus prior cis-RT) and chemotherapy backbone (cisplatin vs carboplatin). This trial will be run in an open label design due to the following considerations: the control arm is the standard of care for women diagnosed with metastatic, persistent or recurrent cervical cancer because of its impact on overall survival and the primary endpoint of the study is overall survival (OS), so blinding is not needed to ensure a robust assessment.

Grupo Español de Investigación en Cáncer de Ovario

Sponsor

Phase 3

Phase

NCT03556839 2018-000367-83, ENGOT-Cx10, GEICO 68-C, JGOG1084, GOG-3030 ENGOT-Cx10 / BEATcc

Eligibility Criteria:

Gender
Female

Age
>=18 Years

Healthy Volunteers
No

How does the BEATcc clinical trial work? This clinical trial is recruiting people who have a type of disease called cervical cancer. In order to take part, patients must have cervical cancer that either has not gone away during previous treatments (known as persistent disease) or have cervical cancer that has previously been treated but has now come back (known as recurrent disease), or newly diagnosed cancer that has already spread to other parts of the body (known as metastatic disease).

The purpose of this clinical trial is to compare the effects, good or bad, of chemotherapy and bevacizumab when given with or without atezolizumab in patients with cervical cancer. In this clinical trial, you will get chemotherapy and bevacizumab, with or without the new treatment atezolizumab. Chemotherapy plus bevacizumab is the current standard 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 cervical cancer that is persistent, recurrent or metastatic.

You must not have previously received full doses of chemotherapy or anti-cancer therapy for your cervical cancer since it has come back or spread to other parts of the body, and you must not have previously been treated with bevacizumab. You cannot join 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.

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.

ForPatients

by Roche

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) and given either:

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

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

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment for as long as it can help you. You are free to stop this treatment at any time. After being given treatment, you will still be seen by the clinical trial doctor after 1 month and then every 3–4 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

Trial-identifier: NCT03556839