ForPatients
by Roche

Endometrial Cancer

A clinical trial to look at how well atezolizumab plus chemotherapy works in women with endometrial cancer

Atezolizumab Trial in Endometrial Cancer - AtTEnd

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	11 Countries	NCT03603184 IRFMN-EN-7556

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 is an engineered humanised monoclonal immunoglobulin G1 antibody that binds selectively to PD-L1 and prevents its interaction with PD-1 and B7-1. In May 2016 atezolizumab was approved by the FDA for patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing chemotherapy, or within 12 months of receiving chemotherapy before surgery (neoadjuvant) or after surgery (adjuvant); in October 2016 it was approved by the FDA for patients with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy, and have progressed on an appropriate FDA-approved targeted therapy if their tumor has EGFR or ALK gene abnormalities. Finally, in April 2017 atezolizumab was granted accelerated approval by FDA for the first-line treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin chemotherapy. Combinations of atezolizumab with chemotherapeutic agents and/or targeted therapies were studied in different solid tumors such as melanoma, NSCLC, renal cell carcinoma and colorectal carcinoma. From these studies the AE profile of atezolizumab combinations were consistent with that of the individual agents. Finally, preliminary results of a Phase Ia study of Atezolizumab (NCT01375842) monotherapy in relapsed endometrial cancer were reported as abstract at ASCO 2017. Fifteen patients were evaluated for safety and efficacy with a minimum follow-up of 11.2 months. No G4-5 related AEs occurred. Regarding efficacy ORR was 13% [2/15] by RECIST. Atezolizumab seemed to have a favorable safety profile, with durable clinical benefit in some patients. Further studies with atezolizumab are warranted given its promising results in advanced endometrial cancer and the limited efficacy of current treatment options.

Mario Negri Institute for Pharmacological Research	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

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

How does the AtTEnd clinical trial work?
This clinical trial is recruiting women who have a particular type of cancer called endometrial cancer. In order to take part, patients must have endometrial cancer that has not been completely treated with surgery (known as residual disease) or have endometrial cancer that has previously been treated, but has now come back (known as recurrent disease).

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab plus chemotherapy versus placebo plus chemotherapy in patients with endometrial cancer. In this clinical trial, you will get either atezolizumab plus chemotherapy (paclitaxel and carboplatin) or placebo plus chemotherapy (paclitaxel and carboplatin). The combination of paclitaxel and carboplatin is the current standard treatment for patients with advanced endometrial cancer.

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.

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 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 endometrial cancer and not have previously received any chemotherapy treatment for advanced cancer.

You must not have had major surgery within 1 month of you joining the trial and 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. 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) and given either:

- atezolizumab given as an infusion into your vein every 3 weeks until your disease is under control plus chemotherapy given as an infusion into your vein every 3 weeks for the first 4 to 6 months
- OR placebo given as an infusion into your vein every 3 weeks until your disease is under control plus chemotherapy given as an infusion into your vein every 3 weeks for the first 4 to 6 months

You will have a two in three chance of being placed in the atezolizumab group and a one in three chance of being placed in the placebo group.

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) for as long as it can help you. You are free to stop this treatment at any time. After being given treatment, you will be seen by the clinical trial doctor within 1 month, then every 3 months during the first year and every 6 months thereafter. 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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