

Cancer

A clinical trial to look at how well RO6874281 works in combination with another drug called atezolizumab to slow, stop or reverse the course of solid tumours

Study to Evaluate the Therapeutic Activity of RO6874281 as a Combination Therapy in Participants With Advanced and/or Metastatic Solid Tumors

Trial Status
Terminated

Trial Runs In
15 Countries

Trial Identifier
NCT03386721 2017-003182-94
BP40234

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

Trial Summary:

This is an open-label, multicenter, basket trial Phase II study to evaluate the antitumor activity of simlukafusp alfa in combination with atezolizumab in participants with advanced and/or metastatic solid tumors. Currently the focus is on participants with Head and Neck, oesophageal and cervical cancers with confirmed squamous cell carcinoma histology type.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT03386721 2017-003182-94 BP40234
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
>= 18 Years

Healthy Volunteers
No

How does the BP40234 clinical trial work?

This clinical trial is recruiting people who have solid tumours (cancer) that are advanced or have spread ('metastatic'). Solid tumours can include lung cancer, cancers of the head and neck, oesophageal (throat) cancer, cervical cancer or a cancer that starts in another organ. Advanced or metastatic are terms used to describe a tumour that has spread beyond the original cancer site to other parts of the body.

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The purpose of this clinical trial is to compare the effects, good or bad, of RO6874281 plus atezolizumab in patients with advanced or metastatic solid tumours. By giving the two drugs together it is hoped that the effects are greater than giving each drug on its own.

In this clinical trial, you will get a combination of RO6874281 plus atezolizumab. The exact treatment schedule will depend on which group you are allocated to (and this depends on your type of cancer and, in some cases, the type of treatment that you have already received for your tumour).

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must have an advanced or metastatic solid tumour, and be at least 18 years old.

You will not be able to take part if your tumour has spread to your brain or spinal cord and (1) you are experiencing symptoms caused by this, or (2) if you haven't yet received treatment for the cancer in your brain/spinal cord.

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, both men and women (if you are not currently pregnant but can become pregnant) 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?

The majority of patients who join this clinical trial will be given RO6874281 plus atezolizumab, with both infused into a vein in your arm. The exact treatment that you will receive depends on the group you are allocated to, but will be based on one of two schedules:

- RO6874281 every week plus atezolizumab every 2 weeks for 4 weeks, then RO6874281 plus atezolizumab every 2 weeks

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- RO6874281 plus atezolizumab every 3 weeks

Your group will depend on your type of cancer, and in some cases, the type of treatment that you have already received. In some groups, you may be randomly allocated to RO6874281 plus atezolizumab or another 'control' treatment. Your study doctor will explain to you your group allocation and the treatment you will receive.

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 helps you. You are free to stop treatment at any time. After being given treatment, you will still be seen regularly by the clinical trial doctor. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having. After being given your last dose, you will be seen by the clinical trial doctor after about 1 month, 3 months and 4 months.

What does the BP40234 clinical trial look like?

1. Can I take part in this clinical trial?

If you find a cell next to your name, your doctor will not be able to see if the clinical trial is suitable for you.



If you have been contacted (directly) that the information of your doctor (profession) and the clinical trial is suitable for you, your doctor will explain the clinical trial and the rights that you have as you can decide if you want to take part.

Your doctor can indicate the general context of the trial and what investigations (blood tests) involve you as a patient that have to be done again.

2. What treatment will I be given?

Randomisation



Most people in the clinical trial will be given two drugs – Olaparib and enzalutamide – both as tablets and by vein.

Your treatment will depend on the type of cancer you have (prostate, breast or other cancer) and whether you have already received, and are taking, or have previously received, other drugs.

You will be given information on your final treatment outcome.



You will be given the treatment to which you have been randomised.

3. What happens during the clinical trial?



After being given treatment, all patients will be seen regularly by the clinical trial doctor to see how you are responding to treatment and to get if you are having any side effects.

You can leave the clinical trial at any time and you will not lose access to your regular care.

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: <https://clinicaltrials.gov/ct2/show/NCT03386721>

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