

Clinical Trial Results Summary

A clinical trial to learn more about the safety of alpelisib when given with fulvestrant in Indian people with advanced breast cancer

Thank you!

Thank you to the participants who took part in the clinical trial for **advanced breast cancer**. Every participant helped to learn more about the trial drug **alpelisib**, also called **BYL719**.

Novartis sponsored this trial. We believe it is important to share what was learned from the results of this trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CBYL719CIN01

Novartis drug studied: **Alpelisib**, also called **BYL719**

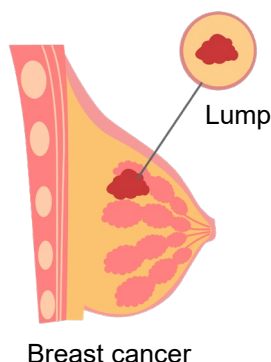
Sponsor: Novartis

- If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

- This summary only shows the results of a single clinical trial. Other clinical trials may have different results.

What was the main purpose of this trial?

The purpose of this trial was to learn more about the safety of **alpelisib** when given with **fulvestrant** in Indian people with **advanced breast cancer** that had progressed during or after receiving an anti-cancer hormone treatment.



Breast cancer happens when cells in the breast start growing uncontrollably and form a lump, which is called a tumor. In **advanced breast cancer**, the cancer cells have spread from the breast to nearby areas or other parts of the body. Breast cancer can cause a wide range of symptoms. The most frequent symptoms of **advanced breast cancer** include:

- Changes in the size, shape, or appearance of one or both breasts
- A lump or swelling in the breast, chest, or armpits
- Shortness of breath
- Bone pain

There are different types of breast cancer. In this trial, participants had the following types of breast cancer:

- **Hormone receptor-positive (HR-positive):** Breast cancer cells have receptors (proteins) that use the hormones estrogen and progesterone to help the breast cancer cells grow.
- **Human epidermal growth factor receptor 2-negative (HER2-negative):** Breast cancer cells do not have high levels of a protein called HER2, which normally helps cancer cells grow and divide. Treatments that target the HER2 protein do not work to treat this type of breast cancer.
- **PIK3CA mutation:** A change (mutation) in the PIK3CA gene, which normally helps to control cell growth. When it changes, cancer cells can grow rapidly and spread.



Alpelisib is an approved treatment for certain types of breast cancer. It works by targeting cancer cells that have a PIK3CA mutation.



Fulvestrant is a type of hormone or endocrine therapy. It works by blocking estrogen receptors or lowering estrogen levels in the body, which can slow down or stop breast cancer cells from growing.



Trial drug

- **Alpelisib**
Pronounced as
AL-PEL-i-sib
- **Fulvestrant**
Pronounced as
Ful-VES-trant

Alpelisib with **fulvestrant** is an approved treatment for **advanced breast cancer** in post-menopausal women as well as in men. Menopause is when women stop having monthly menstruation, also called a period.

This trial was carried out to learn about the safety of **alpelisib** when given with **fulvestrant** in Indian people with **advanced breast cancer** as part of a commitment to the health authority in India.



The trial's purpose was to answer this main question:

- What medical problems, also called adverse events, happened during this trial?
 - ↳ **Adverse events** reported are any sign or symptom that participants had during this trial. Adverse events **may** or **may not** be caused by treatments in the trial.

How long was this trial?



The trial began in August 2022 and ended in June 2025. Each participant was in the trial for up to 8 months. The participants started the trial on different dates.

At the end of this trial, Novartis created a report of the trial results. This summary is based on that report.

Who was in this trial?



40 participants with **advanced breast cancer** received treatment in this trial. All participants were female. Participants' ages ranged from 38 to 81 years. Their average age was 55 years. All participants were Asian.

The participants could take part in this trial if they:

- Were men or post-menopausal women aged 18 years or older
- Had HR-positive and HER2-negative **advanced breast cancer**
- Had a confirmed PIK3CA mutation
- Had cancer that progressed during or after receiving an anti-cancer hormone treatment
- Were fully active or able to do light activities

What treatments did the participants receive?

The treatments in this trial were given in 28-day **cycles**.

The treatments in this trial were:

A **cycle** is a treatment period that is repeated.



Alpelisib - 300 milligrams (mg), taken by mouth as a tablet, once daily.



Fulvestrant - 500 mg, given as an injection into a muscle, on Days 1 and 15 of the first cycle and then on Day 1 of the remaining cycles.

The participants, researchers, and trial staff knew that all participants received **alpelisib** with **fulvestrant**.

What happened during the trial?

Before treatment

Up to 35 days



The trial staff checked to make sure the participants could be in this trial.

During treatment

Up to 6 months

All 40 participants received **alpelisib** with **fulvestrant** during each treatment cycle.



Cycle 1: Participants took **alpelisib** once daily and received **fulvestrant** on Days 1 and 15.



Cycle 2 to Cycle 6: Participants continued to receive **alpelisib** once daily and **fulvestrant** on only Day 1 of each cycle.

After treatment

Up to 1 month



Trial staff checked participants' general health and for any medical problems within 1 month after participants' last dose of trial treatment.



Participants either received a telephone call or visited the trial site.

Trial staff checked the participants' general health throughout the trial.

What medical problems, also called adverse events, happened during this trial?

Trial doctors keep track of all medical problems, also called **adverse events**, that happen in trials. They do this even if they think the adverse events are not related to the trial treatments.

Researchers need results from many trials to decide if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the day participants started the trial treatment until 1 month after the treatment.

An **adverse event** is:

- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, requires hospital care, or results in death

Treatments in the trial **may** or **may not** cause adverse events.

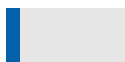


All 40 participants had adverse events, including serious and other adverse events.

- 10 participants had serious adverse events
- 4 participants died due to any cause, including **advanced breast cancer**

The researchers concluded there were no new safety concerns for **alpelisib** when given with **fulvestrant** in this trial.

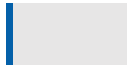
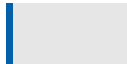
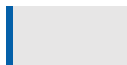
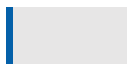
How many participants had adverse events?

	Alpelisib + Fulvestrant 40 participants
Had any adverse event , including serious and other	40 of 40 100% 
Had at least 1 serious adverse event	10 of 40 25% 
Died	4 of 40 10% 

What serious adverse events did the participants have?

10 participants had serious adverse events.

The table below shows the most common serious adverse events.

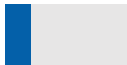
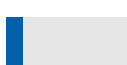
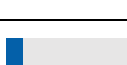
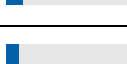
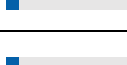
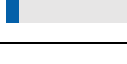
	Alpelisib + Fulvestrant 40 participants
Diarrhea	2 of 40 5% 
Feeling tired Fatigue	2 of 40 5% 
High blood glucose levels Hyperglycaemia	2 of 40 5% 
Shortness of breath Dyspnoea	2 of 40 5% 
Soreness, swelling, or ulcers in the mouth Stomatitis	2 of 40 5% 
Vomiting	2 of 40 5% 

What other (not including serious) adverse events did the participants have?

All participants had other adverse events.

The table below shows the most common other adverse events.

	Alpelisib + Fulvestrant 40 participants
High blood glucose levels Hyperglycaemia	36 of 40 90% 
Soreness, swelling, or ulcers in the mouth Stomatitis	15 of 40 38% 
Diarrhea	14 of 40 35% 
Vomiting	9 of 40 23% 

Alpelisib + Fulvestrant 40 participants		
Decreased appetite	8 of 40 20%	
Feeling sick Nausea	7 of 40 18%	
Feeling tired Fatigue	5 of 40 13%	
Fever Pyrexia	5 of 40 13%	
Weight decreased	5 of 40 13%	
Cough	4 of 40 10%	
Itching Pruritus	4 of 40 10%	
Red skin rash with small bumps Rash maculo-papular	4 of 40 10%	
Swelling in arms or legs Oedema peripheral	4 of 40 10%	
Weakness Asthenia	4 of 40 10%	

What was learned from this trial?

Researchers learned more about the safety of **alpelisib** when given with **fulvestrant** in Indian people with **advanced breast cancer** that had progressed during or after receiving an anti-cancer hormone treatment.



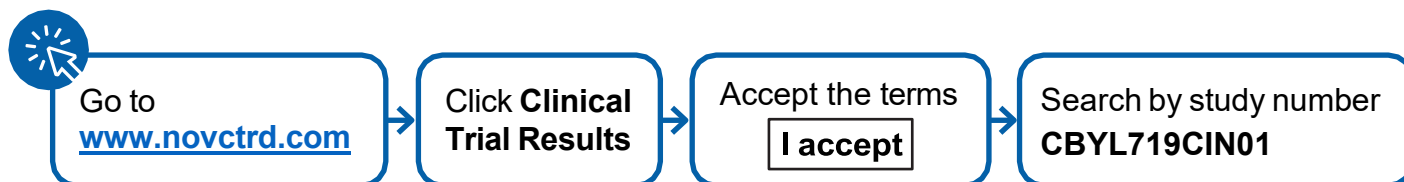
- The researchers concluded that there were no new safety concerns for **alpelisib** when given with **fulvestrant** in this trial.
- The results showed that this treatment can be used in Indian people and may continue to be used, as it is already approved.

When this summary was written, Novartis was considering next steps for **alpelisib**.

Where can I learn more about this trial?

To learn more about the results and adverse events in this trial, read the scientific summary of the results. It is available on the Novartis Clinical Trial Results website, www.novctrd.com.

Follow these steps to find the scientific summary:



For more information about this trial, go to this website:

- clinicaltrials.gov – search using the number **NCT05631795**

Other trials of **alpelisib** may appear on the public websites above. When there, search for **alpelisib** or **BYL719**.

Full clinical trial title: ALPelisib INdia Safety STudy (ALPINIST): A phase IV, prospective, multicenter, open-label, non-comparative, interventional study to assess the safety of alpelisib plus fulvestrant, in men and post-menopausal women with HR-positive, HER2-negative, advanced or metastatic breast cancer (ABC or MBC) with a PIK3CA mutation, whose disease has progressed on or after endocrine based treatment



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