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A plain language summary of the 7-year results from the CROWN study: lorlatinib compared with crizotinib in people with ALK-positive non-small cell lung cancer

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Plain Language Summary of Publication

A plain language summary of the 7-year results from the CROWN study: lorlatinib compared with crizotinib in people with *ALK*-positive non-small cell lung cancer

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Where can I find the original article on which this summary is based?

The original article 'Lorlatinib versus crizotinib as first-line treatment for advanced *ALK*-positive non-small-cell lung cancer: 7-year update from the phase III CROWN study' on which this summary is based was published in *Annals of Oncology*. You can read the original article for free at: https://www.annalsofoncology.org/article/S0923-7534(26)00876-8/fulltext

Summary

How to say (download PDF and double click sound icon to play sound)...

- **Crizotinib:** krih-ZOH-tih-nib
- **Lorlatinib:** lor-LA-tih-nib

What is this summary about?

This is a summary of the results of a study called CROWN. The CROWN study included people with advanced non-small cell lung cancer (NSCLC) who had changes in a **gene** called anaplastic lymphoma kinase, or *ALK,* in their cancer cells. This type of cancer is called *ALK*-positive NSCLC. People participating in the study received a type of medicine, called an ALK inhibitor, as their first treatment. This study looked at the benefits of two ALK inhibitor medicines, called lorlatinib (also called Lorbrena/Lorviqua) and crizotinib (also called Xalkori), to understand if lorlatinib helped control the disease better than crizotinib. It also looked at side effects to determine the safety of the two medicines.

When this study began in April 2017, crizotinib was the standard treatment for people with advanced *ALK*-positive NSCLC. This is why crizotinib was chosen as the medicine to compare with lorlatinib. This choice was discussed and agreed with regulatory agencies, such as the Food and Drug Administration (FDA). This analysis looked at how well lorlatinib and crizotinib worked and their **side effects** in people with advanced *ALK*-positive NSCLC after 7 years in this study.

What are the key takeaways?

In this study, 149 people took lorlatinib and 142 took crizotinib. All the people had advanced *ALK*-positive NSCLC. After observing people for 7 years, researchers found that more people who took lorlatinib were still alive without their cancer getting worse than people who took crizotinib. After 7 years, 66 out of 149 people (44%) were still taking lorlatinib, while only 4 out of 142 people (3%) were still taking crizotinib.

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After 7 years, people who took lorlatinib had a 55% estimated chance of being alive without their cancer getting worse, compared with a 3% estimated chance in people who took crizotinib. These results show how long people lived without their cancer getting worse; they do not show whether people who took lorlatinib lived longer overall. People who took lorlatinib and were alive without their cancer getting worse in the first 24 months of treatment had a 79% estimated chance of being alive without their disease getting worse after 7 years.

The most common side effects in people who took lorlatinib were high levels of cholesterol and high levels of triglycerides (a type of fat) in the blood and edema (swelling). Between 5 and 7 years of treatment, none of the people taking lorlatinib had to stop taking it and not restart it to manage side effects. Everyone who stopped taking lorlatinib and did not restart it to manage side effects related to lorlatinib did so in the first 26 months of treatment. The types of side effects reported after 7 years and how often they happened were similar to the side effects reported after 5 years.

Gene: A part of the DNA that has instructions for making things your body needs to work.

Side effect: An unwanted effect of a medicine that is beyond its desired effect. Side effects can be harmful. These occur while taking a medicine and may or may not be related to the medicine.

What were the main conclusions reported by the researchers?
The 7-year results from this study showed that more people who took lorlatinib continued to live longer without their cancer getting worse compared with people who took crizotinib. After being observed for an average of 7 years, more than half of the people who took lorlatinib are still alive without their cancer getting worse.

Lorlatinib also showed long-lasting effects in the brain, with no new cancer growth observed in the brain after the first 30 months of treatment. This means that most people with advanced *ALK*-positive NSCLC who participated in this study were able to be treated with lorlatinib for a long time to keep their disease from getting worse or spreading to the brain. A summary of what the findings mean to the *ALK*-positive NSCLC patient community is included at the end of this plain language summary.

What is the purpose of this plain language summary?

The purpose of this plain language summary is to help you understand the findings from the recent analysis of the CROWN study.

This summary reports the results of a single study. The results of this study may differ from those of other studies. Healthcare professionals should make treatment decisions based on all available evidence, not on the results of a single study.

This study described is still ongoing; therefore, the final outcomes of this study may differ from the outcomes described in this summary. Lorlatinib and crizotinib are both approved to treat the condition that is discussed in this summary.

Who is this article for?

This summary was written to help people with *ALK*-positive NSCLC, their care partners, and healthcare professionals understand the 7-year results of this study.

Who sponsored this study?

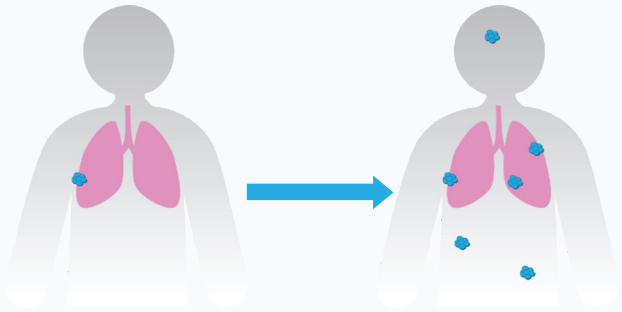
This study was **sponsored** by Pfizer.

Sponsor: A company or organization that oversees and pays for a clinical research study. The sponsor also collects and analyzes the information from the study.

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What is advanced *ALK*-positive NSCLC?

- Non-small cell lung cancer, or NSCLC, is the most common type of lung cancer.
- NSCLC that has spread from the lung to other parts of the lungs or body is called advanced or metastatic NSCLC.



- Some people with NSCLC have changes in a gene called anaplastic lymphoma kinase, or *ALK*, in their cancer cells. This type of cancer is called *ALK*-positive NSCLC.
- The *ALK* gene makes the ALK protein, which controls how cells grow. If there is a change in the *ALK* gene, the ALK protein does not work properly. This can cause cells to grow out of control and lead to cancer.
- Changes in the *ALK* gene are found in about 3 to 7 out of every 100 people (3% to 7%) with NSCLC. This type of cancer is called *ALK*-positive NSCLC.
- People with *ALK*-positive NSCLC have a high chance of the cancer spreading to the brain.
- It is hard for some medicines to reach the brain, which makes it harder to treat cancer in the brain.

What are ALK inhibitors?

ALK inhibitors are a type of medicine used to help control *ALK*-positive NSCLC. They are typically the first type of medicine used to treat people with advanced *ALK*-positive NSCLC. ALK inhibitors work by blocking the ALK protein, which helps stop cancer cells from growing and spreading.

- **Crizotinib** was the first ALK inhibitor medicine used in people with advanced *ALK*-positive NSCLC. At the time this study started, it was the recommended treatment for people with advanced *ALK*-positive NSCLC, which is why it was chosen as the medicine to compare with lorlatinib in this study.
- **Lorlatinib** is a newer type of ALK inhibitor medicine. Other studies have shown that in people with *ALK*-positive NSCLC, lorlatinib may help more than other ALK inhibitors. Lorlatinib can get into the brain easier than other ALK inhibitors. This means that lorlatinib can help keep tumors from spreading to the brain and can help fight tumors that have already spread to the brain.

Lorlatinib and crizotinib are both ALK inhibitors approved to treat people with advanced *ALK*-positive NSCLC.

What type of study is this study?

This is a **randomized phase 3 clinical study.** The study compares how well two ALK inhibitor medicines, lorlatinib and crizotinib, work to control cancer and how safe they are in people with *ALK*-positive NSCLC.

In this study, people were assigned at random to take one of two treatments. The two study treatments were:

- Lorlatinib taken as tablets by mouth once a day and started at a dose of 100 mg.
  - » If people experienced side effects, the dose could be lowered to 75 or 50 mg daily to manage them.
- Crizotinib taken as capsules by mouth and started at a dose of 250 mg twice a day.
  - » If people experienced side effects, the dose could be lowered to 200 mg twice a day or 250 mg once a day to manage them.



Randomized clinical study: A research study in which the people are placed into different groups so that researchers can compare different study treatments. People are placed into the groups at random (by chance, which is like flipping a coin or rolling dice).

Phase 3 clinical study: A research study that tests how safe a new treatment is and how well it works compared with a standard treatment.

What does this study look at?

In the current snapshot of this study, researchers wanted to know how well lorlatinib worked compared with crizotinib after 7 years. They looked at the following questions:

- How many people were alive without their cancer getting worse?
- How long did at least half the people live without their cancer getting worse?
- How long did it take for the tumors that had spread to the brain to get worse or for new tumors to spread to the brain in at least half of the people?
- What were the most common side effects?

After 7 years in the study, researchers looked at the following questions in people who took lorlatinib:

- How many people reduced their dose or stopped lorlatinib treatment to manage side effects?
- Did lorlatinib work differently in the people who had their dose reduced in the first 26 weeks of treatment?
- What were the results from the **biomarker analysis?**

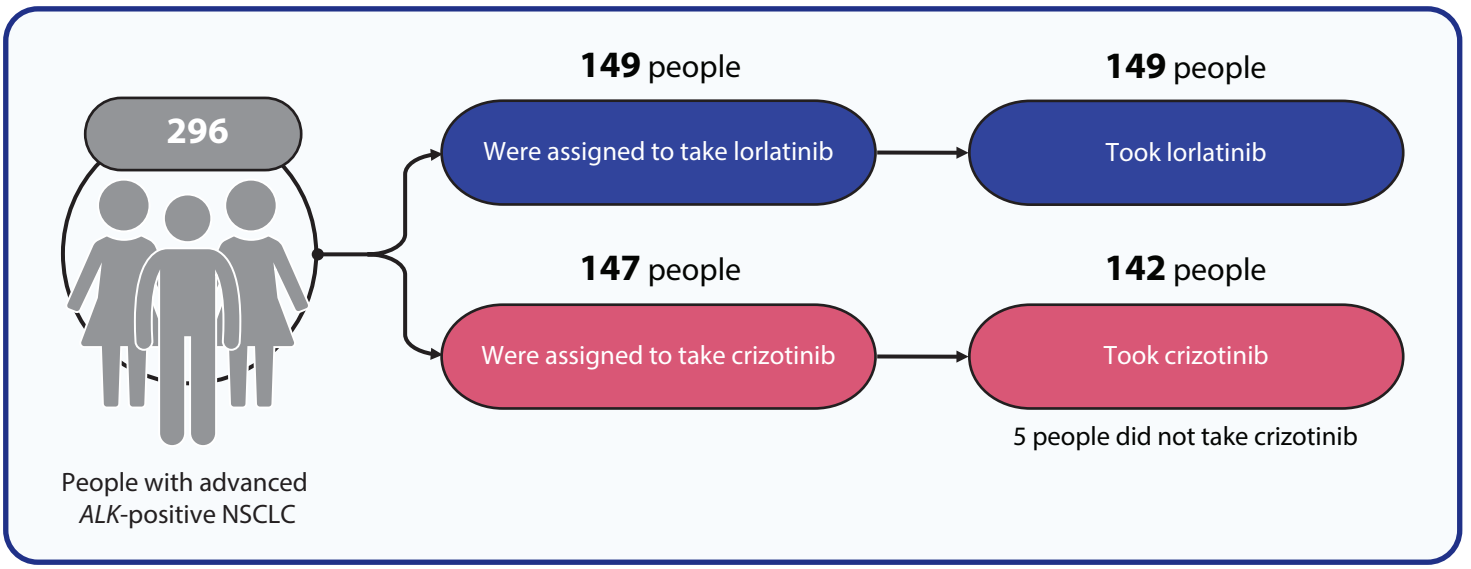


Biomarker analysis: Testing for the presence of biomarkers, which are biological molecules, such as DNA changes, that may help cancerous cells grow and spread rapidly. Testing for the presence of biomarkers may help determine the best individualized treatment options.

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Who took part in this study?

A total of 296 people with advanced *ALK*-positive NSCLC who had not been treated before took part in this study.



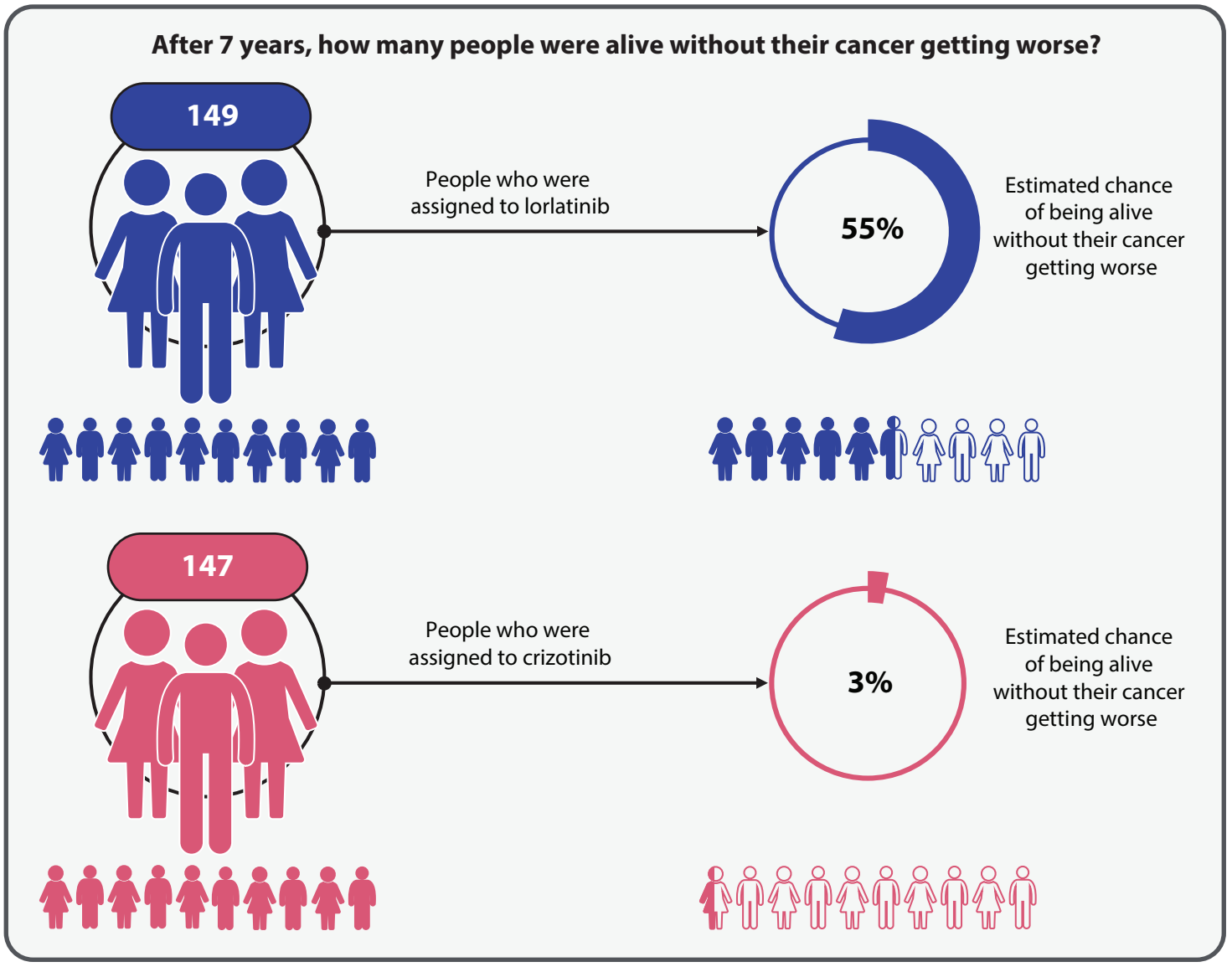
People joined this study between April 2017 and February 2019. This study is ongoing, which means that people continue to be observed over time, whether or not they are still taking the study treatment.

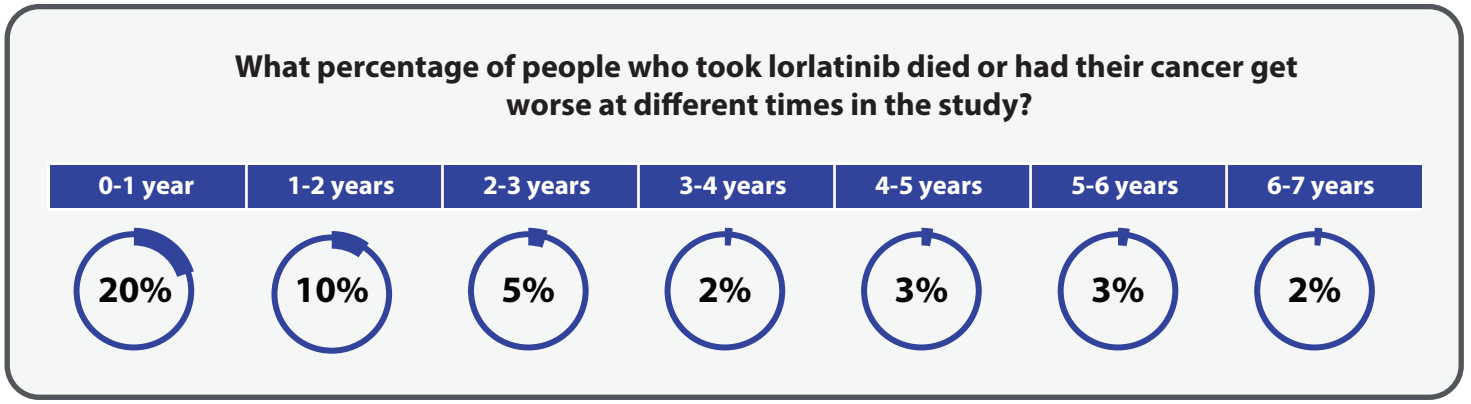
Based on the earlier study results after 5 years of observation, people who took lorlatinib lived longer without their cancer getting worse compared with people who took crizotinib. The current analysis is an update looking at the longer-term benefit after 7 years of observation.

What did the researchers find out in this study?

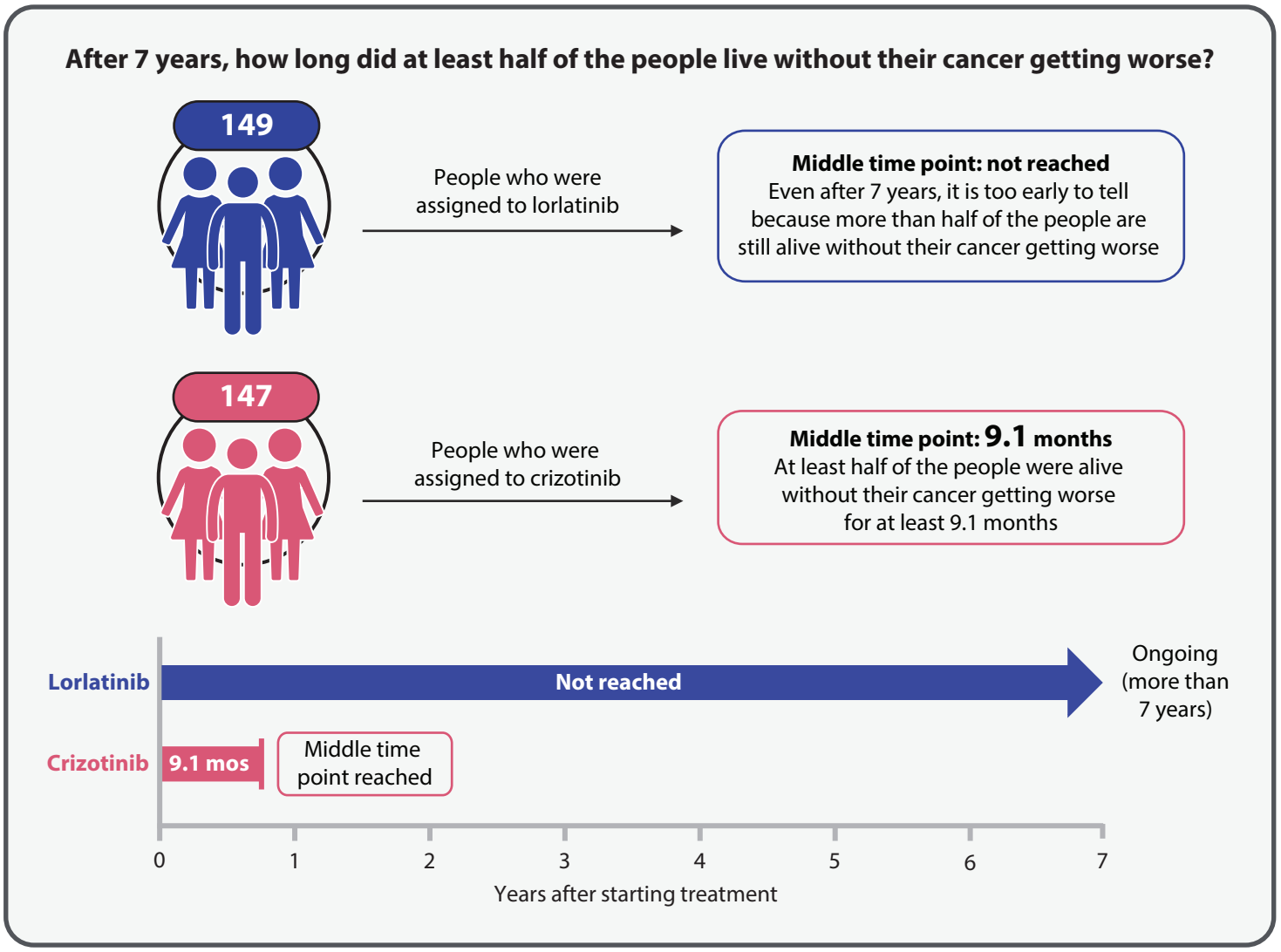
For this 7-year analysis, researchers involved in the study assessed how long people were alive without their cancer getting worse. At the time of this updated analysis on October 31, 2025, people were observed for an average of 7 years.

- 66 out of 149 people (44%) treated with lorlatinib are still taking lorlatinib.
- 4 out of 142 people (3%) treated with crizotinib are still taking crizotinib.

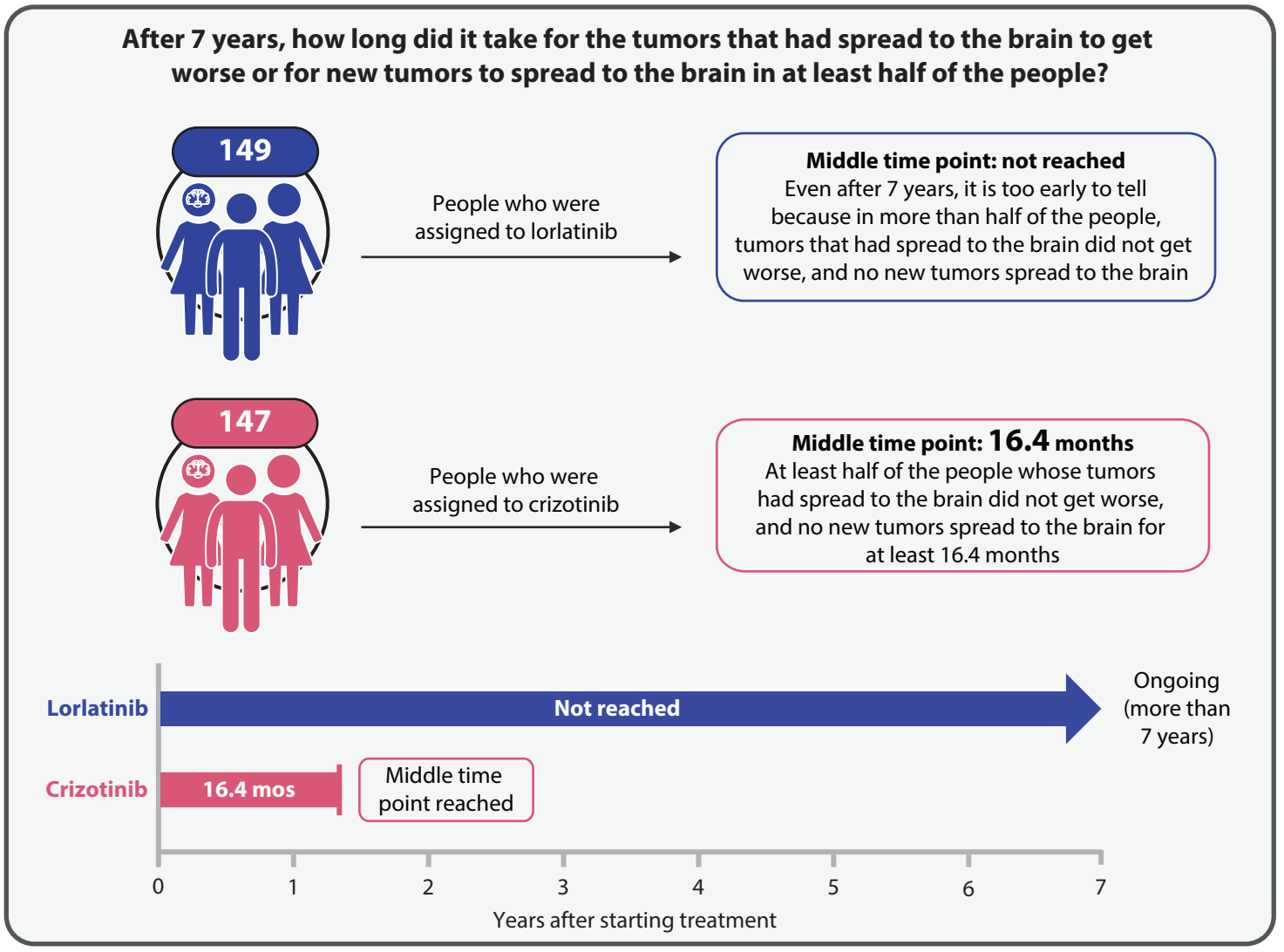




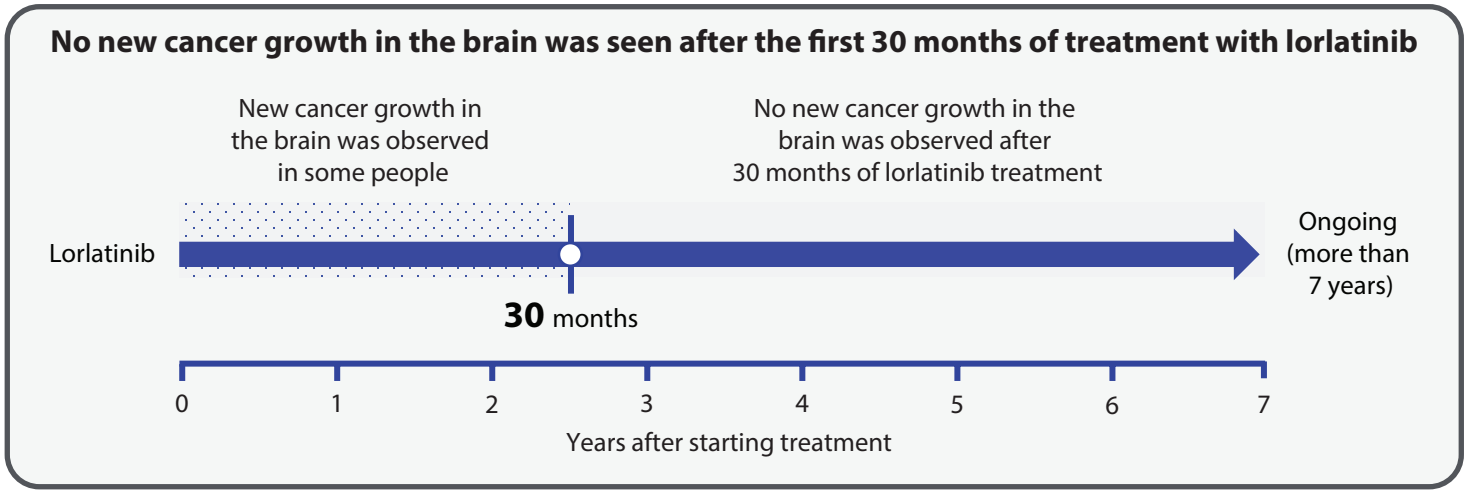
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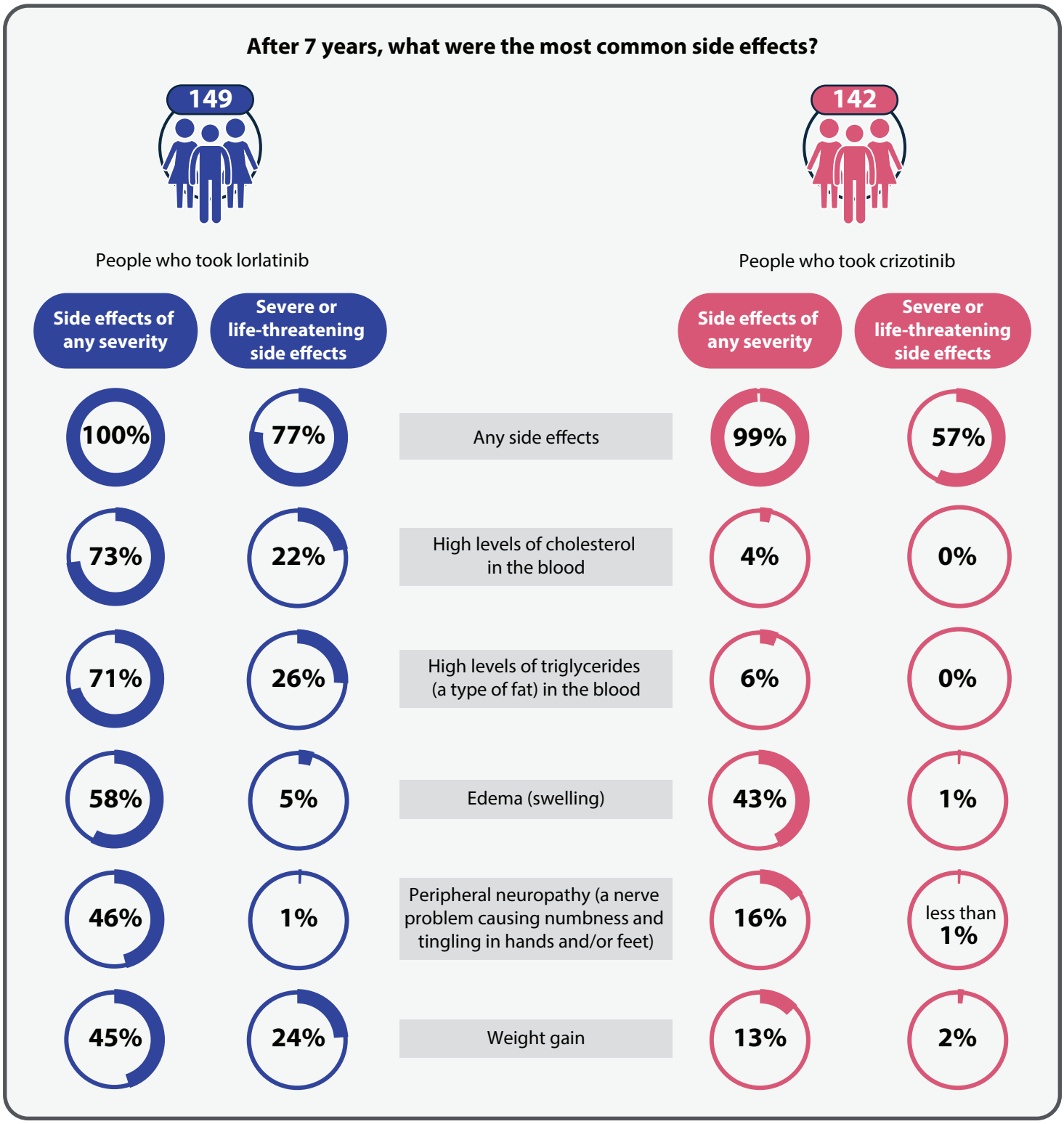
More than half of the people who took lorlatinib were still alive without their cancer getting worse after 7 years.



In more than half of the people who took lorlatinib, tumors that had spread to the brain did not get worse, and no new tumors spread to the brain after 7 years. These results were similar whether or not people had tumors that had spread to the brain at the start of the study.

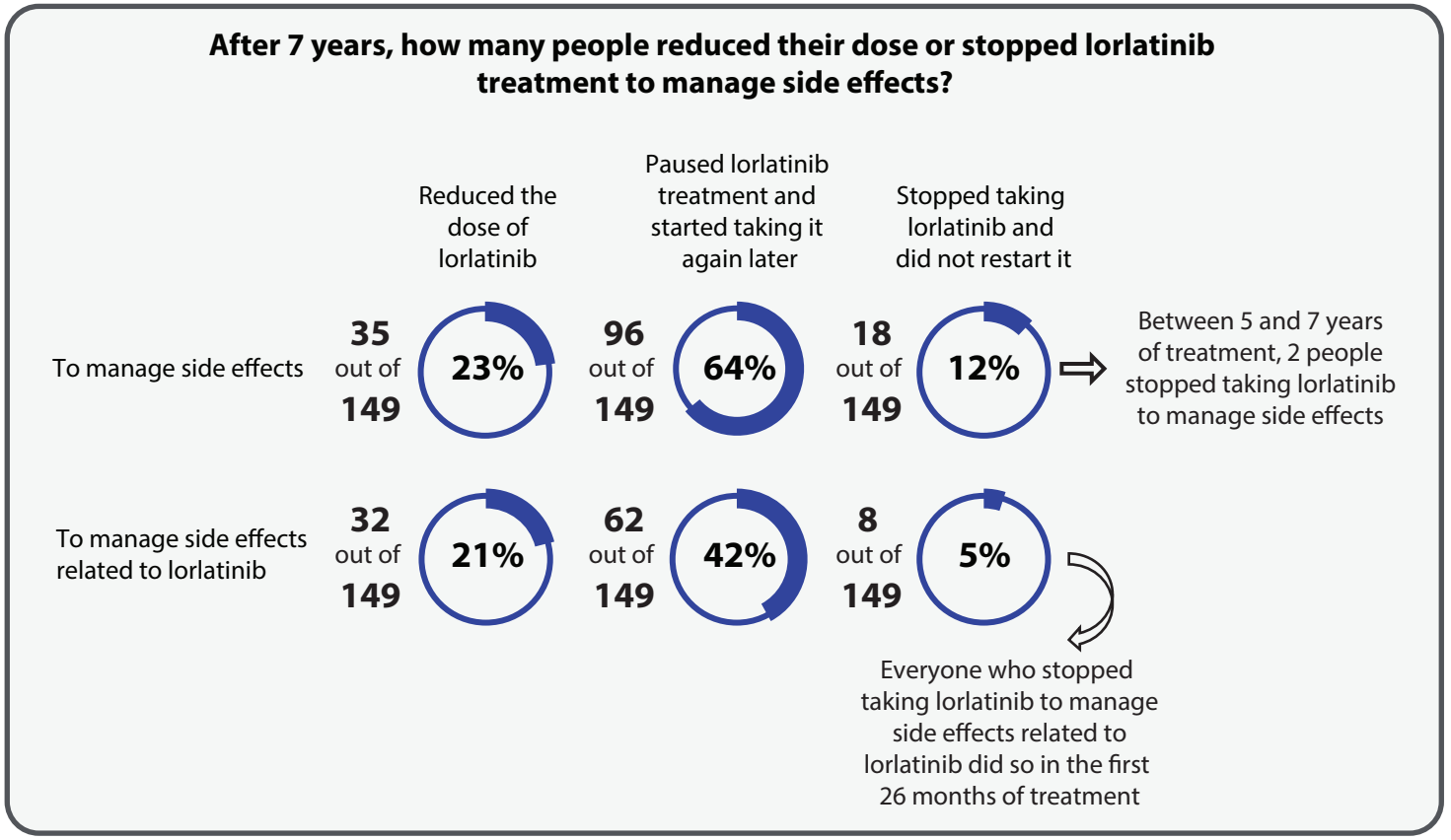


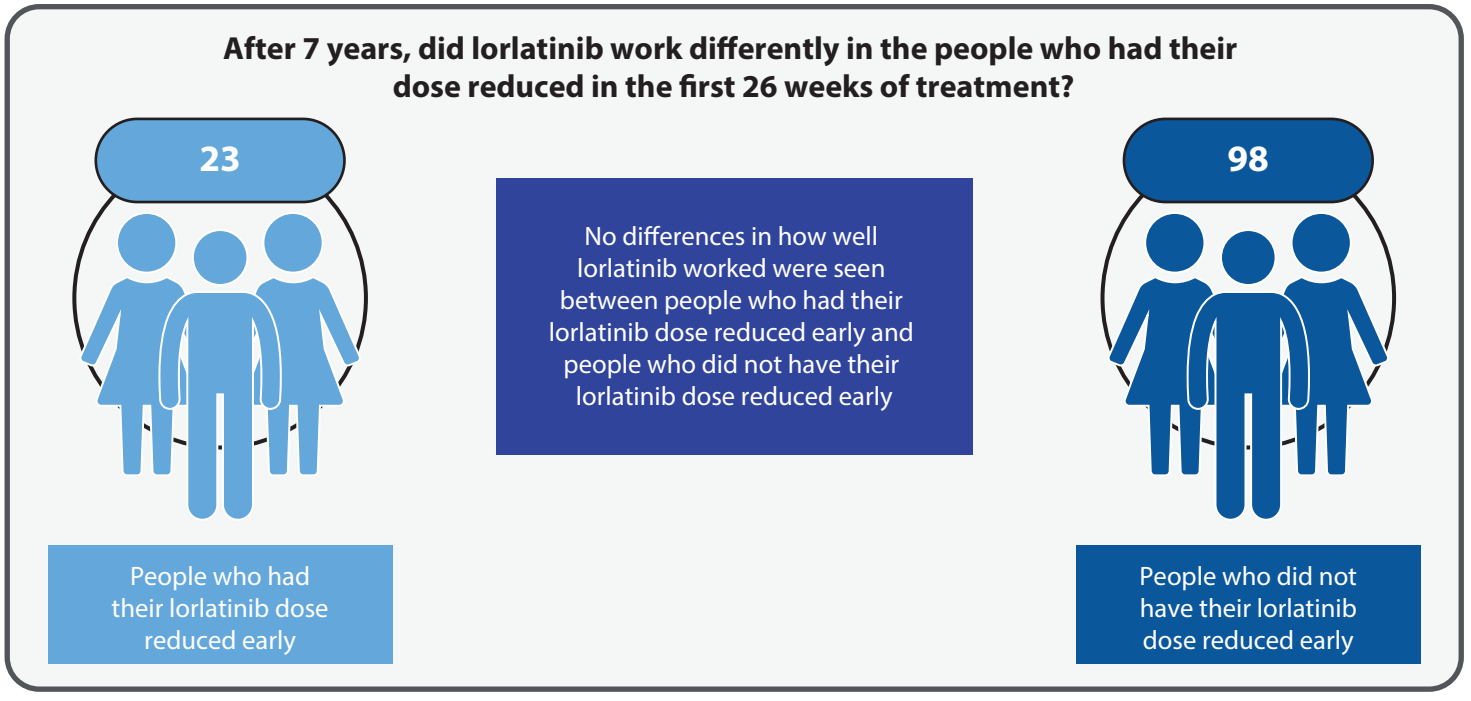
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High levels of cholesterol and triglycerides (a type of fat) in the blood and edema (swelling) were the most common side effects with lorlatinib.

The following results are only for the people who took lorlatinib.





In both groups, people continued to live without their cancer getting worse after 7 years. Therefore, in this exploratory comparison, reducing the lorlatinib dose early did not appear to reduce how well lorlatinib worked, even after 7 years.

Why were biomarkers studied?

A biomarker is a measurable biological sign or indicator in the body that can provide information about a normal or abnormal process, a disease, or how the body responds to treatment. In this study, researchers looked at changes in genes as biomarkers to help understand how cancer responds to treatment. Doctors can use blood tests to detect these changes in genes. Studying these changes may help researchers learn whether blood tests could one day help predict how people will respond to treatment.

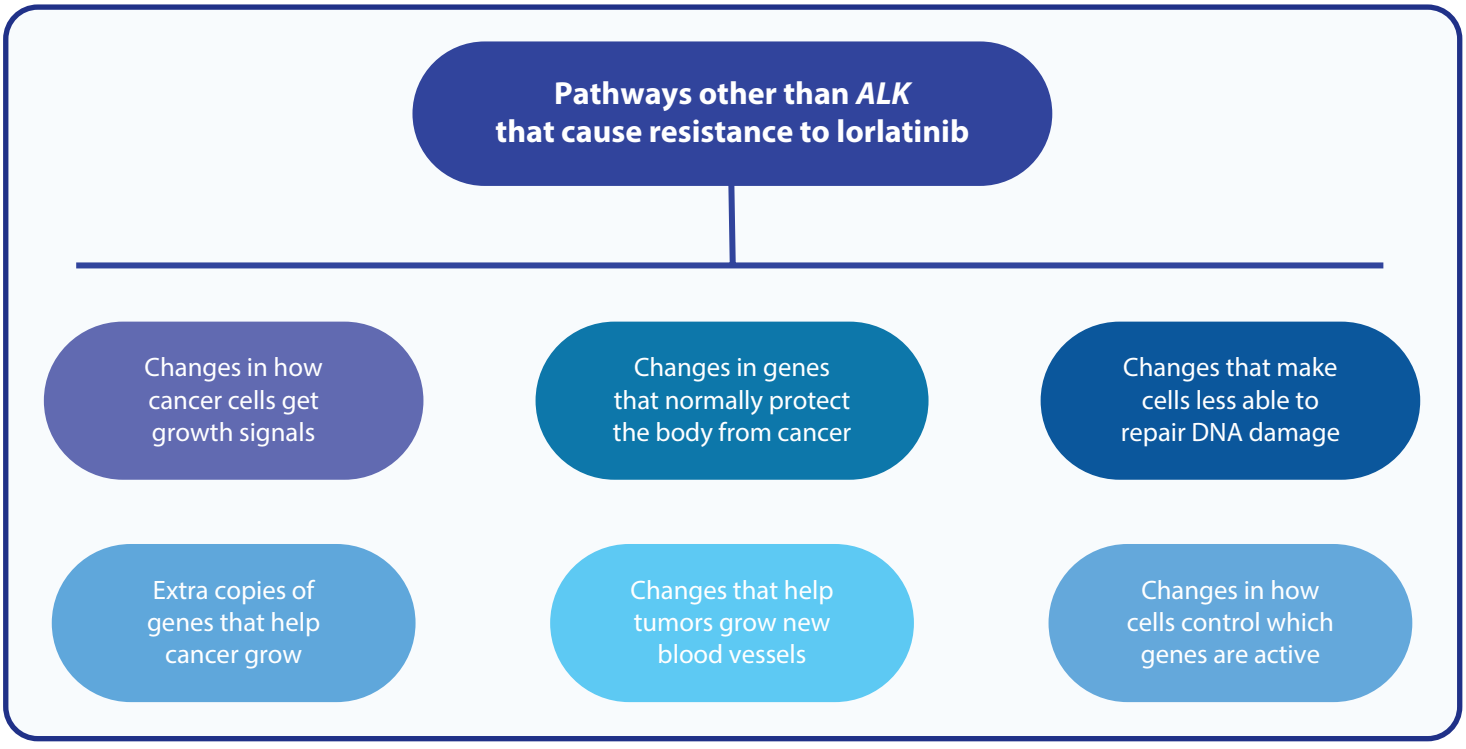
Over time, changes in the *ALK* gene (DNA mutations) can sometimes occur and cause cancer to stop responding to treatment and allow the cancer to grow again. This is known as drug resistance.

Pathway: A group of proteins that work together to complete a specific task in the cell. The proteins typically work in a series of steps with each protein activating the next protein. In this instance, the pathway of proteins is working together to help cells grow.

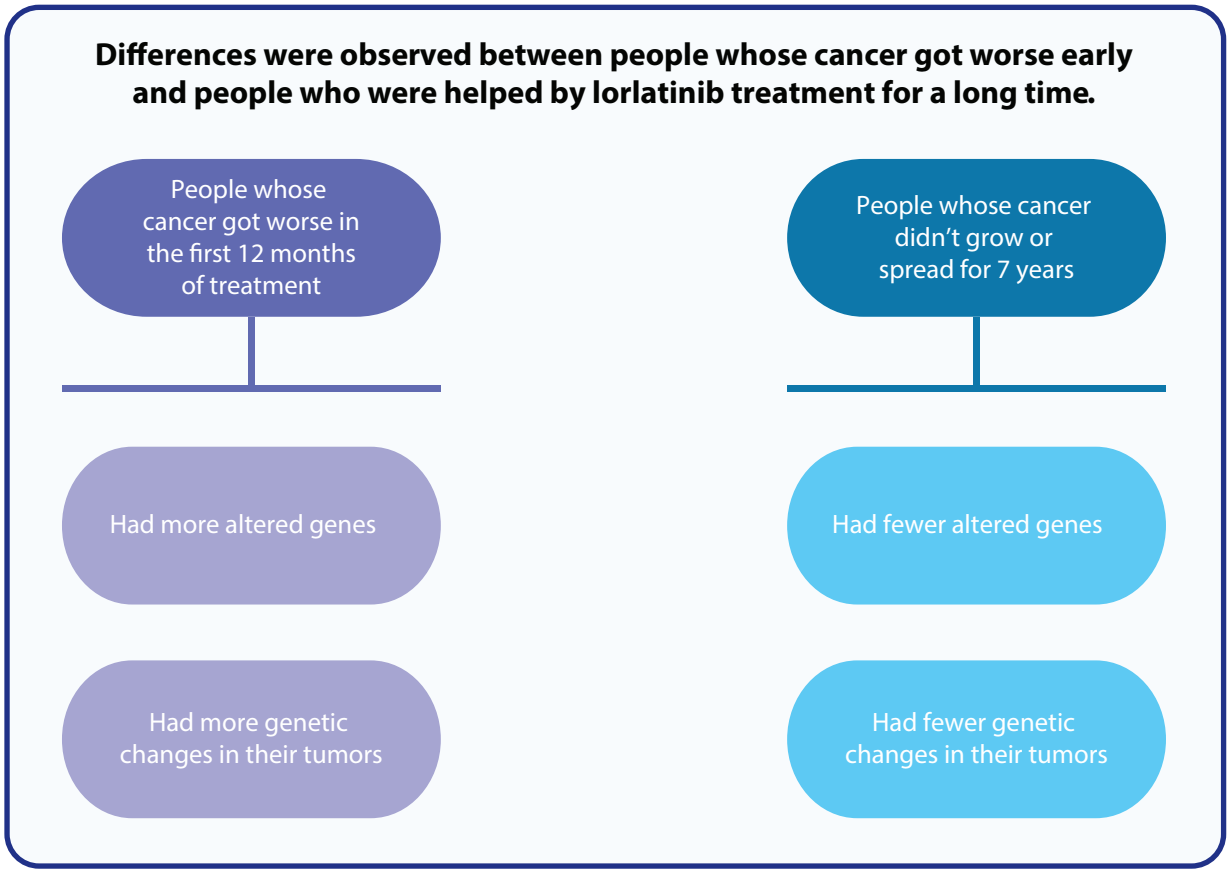
Drug resistance can also be caused by cancer cells finding another way to help cells grow. The cancer cells can turn on other groups of proteins (or **pathways**) that keep cells growing even if the ALK protein pathway remains blocked.

What were the results from the biomarker analysis?

- When blood samples were tested from 23 people in this study at the end of lorlatinib treatment, no new *ALK* gene changes were found that were related to drug resistance.
- Researchers found that when lorlatinib stopped working, it was usually because the cancer found other ways to grow (other pathways), and not because of new changes in the *ALK* gene.



- Blood samples collected before starting lorlatinib showed differences between people whose cancer got worse early and people who were helped by treatment for a long time.
  - » People whose cancer got worse early tended to have more gene changes at the start of treatment, especially in a gene called *TP53*.
- Overall, lorlatinib kept cancer under control longer than crizotinib in people with and without *TP53* gene changes and across different *ALK* gene types.



These biomarker results are **exploratory** and ongoing. These results help researchers better understand why cancer may respond differently to lorlatinib treatment in different people. Although people whose cancer got worse early tended to have more altered genes and more genetic changes in their tumors, this does not mean that researchers can predict exactly what will happen for each person or that people can take a specific action based on these findings right now. More research is needed, and there are no definitive answers at this time.

Exploratory results: The study was not set up to formally make conclusions based on these results. Instead, these results are used to create questions to be investigated with future research.

What do the findings of this study mean?

After being observed for an average of 7 years in the CROWN study, more people who took lorlatinib continued to live without their cancer getting worse than people who took crizotinib.

Among people who took lorlatinib, 2 out of every 10 people (20%) had their cancer get worse or died in the first year, and 1 out of every 10 people (10%) had their cancer get worse in the second year. After this, people taking lorlatinib had a low chance of their cancer getting worse.

In people treated with lorlatinib, the chance of their cancer getting worse was highest in the first 2 years and then became lower and stayed low over time.

People who had their lorlatinib dose reduced early in treatment had similar results as people who did not have their lorlatinib dose reduced early. In both groups, people continued to live without their cancer getting worse after 7 years.

At the end of lorlatinib treatment, no new *ALK* gene changes were found that were related to drug resistance. Resistance likely develops through other pathways.

People whose cancer got worse earlier had more genetic changes in their tumors at the start of lorlatinib treatment compared with people who were helped long-term by taking lorlatinib.

What do the CROWN study data mean for the *ALK*-positive NSCLC patient community?

For many years, patients with *ALK*-positive NSCLC have needed treatments that can help protect the brain and control cancer for longer, while also having side effects that can be managed over time. From the patient's perspective, these needs are closely connected: a treatment needs to work well, but it also needs to support daily life, future planning, and quality of life. The CROWN results help speak to these important treatment needs that matter to patients.

Based on their experiences, Debra and Nancee, patient authors of this plain language summary, reflected on what the 7-year CROWN results may mean for people living with *ALK*-positive NSCLC and their care partners. The perspectives below reflect the patient authors' experiences and may include external evidence, advice, and broader considerations beyond the findings reported in this study.

Protecting the brain

- For many of us living with *ALK*-positive NSCLC, the possibility of cancer spreading to the brain is one of the most frightening parts of the disease. This fear is not only about cancer worsening. It is also about what brain involvement could mean for our independence, memory, communication, work, relationships, and how family and friends may see or experience us living with cancer.
- Because of this, protecting the brain is an important treatment goal for many of us. In fact, patients with *ALK*-positive NSCLC have consistently reported that preventing cancer from spreading to or within the brain is their most important treatment goal, even outweighing the goal of avoiding side effects. For some of us, finding out our cancer had spread to the brain was a more emotional experience than finding out we had cancer in the first place. This news can bring a fear of the unknown and uncertainty about what will happen next and whether treatment will help.
- The 7-year CROWN results showing long-lasting cancer control in the brain with lorlatinib treatment may bring reassurance to the *ALK*-positive community. At the same time, we should still receive ongoing brain monitoring to ensure that if there is disease worsening, it will be caught early. We should have open conversations with our healthcare team about brain health, side effects, and how we are feeling during treatment.

Achieving long-lasting treatment benefit

- For the *ALK*-positive patient community, the finding that the middle time point that people lived without their cancer getting worse had still not been reached after 7 years with lorlatinib treatment is highly meaningful. Not long ago, living 5 years after a diagnosis of advanced *ALK*-positive lung cancer was considered a major milestone, even if the cancer had gotten worse during that time.
- These results may open new conversations about survivorship and long-term planning. This can mean more than simply extra time for us. It can mean being able to imagine participating in future family events, celebrations, careers, fertility decisions, and other life goals that may have once felt unlikely after a cancer diagnosis.
- At the same time, we recognize that not everyone will have the same experience. In some people, the cancer may get worse earlier, so continued monitoring and honest discussions with the healthcare team remain important. For those of us who are doing well on treatment, reaching the first few years without our cancer getting worse may bring more confidence and hope when thinking about the years ahead.

For more information, see 'Patient and oncologist preferences for *ALK*+ advanced non-small cell lung cancer tyrosine kinase inhibitor treatments: a discrete choice experiment in the United States,' which can be found at: https://www.lungcancerjournal.info/article/S0169-5002(25)00742-1/fulltext

Managing side effects over time

- For us, long-term benefit is most meaningful when we feel prepared by knowing what potential side effects to expect before starting treatment and when we can also manage treatment in our daily lives. Understanding side effects, knowing when to speak up, and having support from our healthcare team and care partners can help us feel more prepared and more in control of our life and disease, and can also help us get the most benefit from treatment.
- We may benefit from talking with our healthcare team before and during treatment about possible side effects, how they can be managed, and whether dose changes may be needed.
- The CROWN results suggest that reducing the lorlatinib dose to manage side effects or adjusting the treatment plan does not necessarily mean that the treatment will stop working or that the long-term benefit will be affected. We should not feel like we need to tolerate side effects for the treatment to work and should discuss options with our healthcare team.
- Patient support groups can provide a space for shared experiences, where we can learn from other patients who have gone through treatment and may be better able to recognize, track, and discuss potential side effects. Care partners, family, and friends can also play an important role. Both sources of support may help us notice changes over time, keep track of symptoms or side effects, and support conversations with our healthcare team. For many of us, being informed, supported, and involved in decisions helps us feel more empowered as we live with *ALK*-positive NSCLC.

For more information, see 'Managing lorlatinib together: An overview and practical guide for patients by *ALK*-positive NSCLC patients and medical experts,' which can be found at: https://www.lungcancerjournal.info/article/S0169-5002(25)00554-9/fulltext

Where can I find more information?

- The original article by Shaw AT, *et al*., titled 'Lorlatinib versus crizotinib as first-line treatment for advanced *ALK*-positive non-small cell lung cancer: 7-year update from the phase III CROWN study.' *Ann Oncol*. Published online May 29, 2026. doi:10.1016/j.annonc.2026.05.692. You can read the full article for free at: https://www.annalsofoncology.org/article/S0923-7534(26)00876-8/fulltext
- For more information about the CROWN study (clinical trial number NCT03052608), please visit the ClinicalTrials.gov website at: https://clinicaltrials.gov/study/NCT03052608
- This plain language summary is related to the following previously published plain language summaries:
  - https://www.tandfonline.com/doi/full/10.1080/14796694.2024.2406117
  - https://www.tandfonline.com/doi/abs/10.2217/fon-2022-1289
  - https://www.tandfonline.com/doi/abs/10.2217/fon-2021-0904

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Disclosure statement

Alice T. Shaw reports prior employment with Novartis Institutes for BioMedical Research and employment of a family member with Amgen; consulting or advisory roles with Alterome Therapeutics, Astellas Pharma, BridgeBio, Genentech/Roche, Merck, Novartis, Nuvalent, Pfizer, Revolution Medicines, Rigel, Tango Therapeutics, and Triana Biomedicines; stock or ownership interests in Novartis Institutes for BioMedical Research; research funding from Bristol Myers Squibb; travel, accommodations, and expenses from Amgen and Novartis Institutes for BioMedical Research; and other relationships with EcoR1 and Nextech Invest. Benjamin J. Solomon reports consulting or advisory roles with Amgen, AstraZeneca, BeiGene, Bristol Myers Squibb, GlaxoSmithKline, Johnson & Johnson/Janssen, Lilly, MSD, Nuvalent, Pfizer, Roche/Genentech, and Takeda; and honoraria from Amgen, AstraZeneca, MSD, Pfizer, and Roche/Genentech. 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