

Association between tumor shrinkage and efficacy of lorlatinib in the CROWN study

The full title of the scientific abstract is: Depth of response and progression-free survival in patients with advanced *ALK*-positive non-small cell lung cancer treated with lorlatinib

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Date of summary:
May 2025

- **Study number:** NCT03052608



Study start date:
April 2017

Study end date:
December 2028

For more information on this study, go to:

<https://clinicaltrials.gov/study/NCT03052608>

KEY TAKEAWAY

What are the key takeaways from this study?

- In the CROWN study, people with a type of lung cancer (called *ALK*-positive NSCLC) who took **lorlatinib** showed that the more a tumor shrank, the longer the people survived without their cancer getting worse.

PHONETICS

Find out how to say medical terms used in this summary

Lorlatinib

< lor-LA-tih-nib >

Crizotinib

< krih-ZOH-tih-nib >

Metastatic

< meh-tuh-STA-tik >

ALK gene

< a-ell-kay jeen >

GLOSSARY

Cancer: abnormal cells that grow and divide without control and can spread to other parts of the body

Depth of response: how much a tumor shrinks in size from the time a person starts treatment

Gene: a part of our genetic material (DNA) that contains information for making a specific protein. Proteins are substances that help the body to function

Metastatic: cancer that has spread from the place where it started to another part of the body

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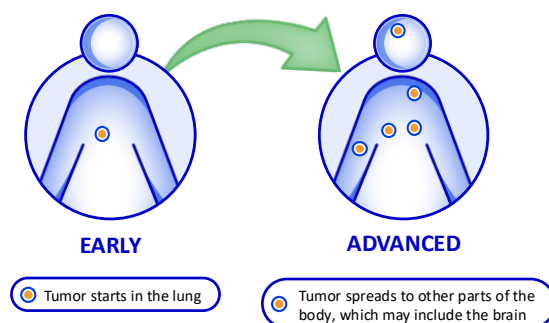




What does this study look at?

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 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.
- 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 leads to problems with cell growth that can cause cancer.
- Changes in the *ALK* gene are found in around 3 to 7 of every 100 people (3%-7%) with NSCLC. This type of cancer is called *ALK*-positive NSCLC.
- People with advanced *ALK*-positive NSCLC have a high chance of the cancer spreading to the brain.



What are lorlatinib and crizotinib?

- **Lorlatinib** and **crizotinib** are types of medicines known as *ALK* inhibitors, which are approved to treat *ALK*-positive NSCLC. These medicines stop cancer cells from growing and spreading by blocking the actions of proteins like *ALK*.
- **Crizotinib** is the first *ALK* inhibitor that was used in people with *ALK*-positive NSCLC.
- **Lorlatinib** is a newer type of *ALK* inhibitor.

What is the CROWN study?

- In the CROWN study, researchers are looking at the effects of two *ALK* inhibitors, **lorlatinib** and **crizotinib**. The study is ongoing, which means that people continue to be observed, whether they continue to take the study treatment or have stopped treatment.
- In this study, people were assigned at random to one of two treatment groups to take a specific study medicine. "Random" means by chance, like flipping a coin. The two study medicines were:
 - **Lorlatinib**, taken as tablets by mouth once a day
 - **Crizotinib**, taken as capsules by mouth twice a day
- In this study, after being observed for 5 years since starting treatment, people who took **lorlatinib** lived longer without their cancer getting worse than people who took **crizotinib**.

In this study, researchers wanted to find out...

- How much did people's tumors shrink after starting lorlatinib treatment, and was the amount of tumor shrinkage associated with people living longer without their cancer getting worse?





Who took part in this study?

- A total of 296 people with advanced *ALK*-positive NSCLC who had not previously been treated for lung cancer took part in the CROWN study.



- This summary shows results from the **lorlatinib** group only.
- People in this study were observed up to 5 years after starting treatment.

RESULTS

How many people treated with lorlatinib could be tested for their depth of response?

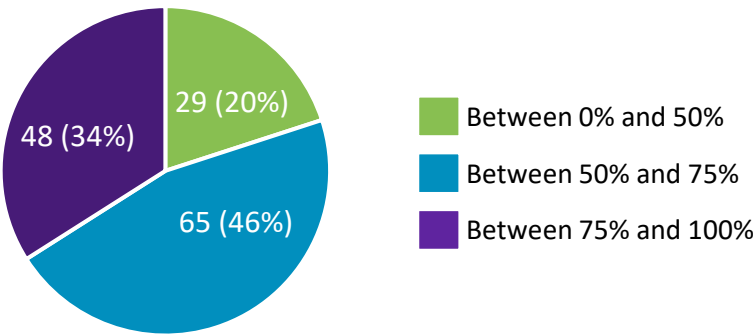
- People could be evaluated if:
 - They had a tumor that could be accurately measured in size at the start of their **lorlatinib** treatment.
 - They had 1 or more follow-up assessments of the tumor.
- 142 of the 149 people (95%) treated with **lorlatinib** were included in this analysis.



What were the results of this study?

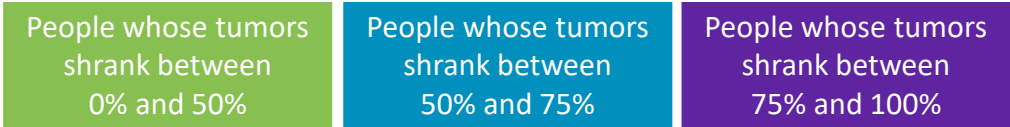
Of the 142 people who were evaluated, how much did their tumors shrink?

- 29 people had their tumor shrink between 0% and 50%
- 65 people had their tumor shrink between 50% and 75%
- 48 people had their tumor shrink between 75% and 100%

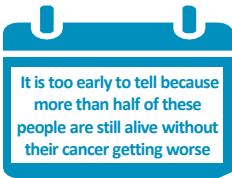


Were the people in the different groups similar at the start of the study?

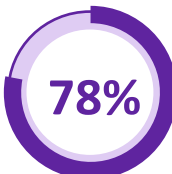
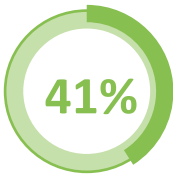
- The groups were similar, except that there were more people whose cancer had spread to their brain at the start of treatment in the group who had their tumors shrink by more than 75%.



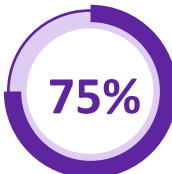
How long were at least half of the people alive without their cancer getting worse?



After 3 years, how many people were alive without their cancer getting worse?



After 5 years, how many people were alive without their cancer getting worse?





What were the main conclusions of this study?

- In the CROWN study, 95% of the people with *ALK*-positive NSCLC treated with **lorlatinib** were evaluated for how much their tumors shrank in size.
 - For people whose tumors had shrunk by less than 50%, 37% of people were alive without their cancer getting worse at 5 year.
 - For people whose tumors had shrunk between 50% - 75%, 62% of people were alive without their cancer getting worse at 5 year.
 - For people, whose tumors shrank by more than 75%, 75% of people were alive without their cancer getting worse at 5 year.
- These findings showed that, in people with *ALK*-positive NSCLC treated with **lorlatinib**, the more a tumor shrank in size, the longer the people lived without their cancer getting worse.

This summary reports the results of a single study. The results of this study may differ from those of other studies. Health 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 approved to treat the condition under study that is discussed in this summary.

MORE INFORMATION

Who sponsored the study?

This study was sponsored by Pfizer Inc.

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The sponsor thanks everyone who took part in this study.

Where can I find more information?

For more information on this study, please visit:

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<https://clinicaltrials.gov/study/NCT03052608>

For more information on clinical trials in general, please visit:

<https://www.clinicaltrials.gov/study-basics/learn-about-studies>

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are>

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