Effect of lorlatinib in people with advanced lung cancer who have received previous treatments

The full title of this abstract is: Efficacy and safety of lorlatinib in patients with *ALK*+ metastatic non-small cell lung cancer (mNSCLC) previously treated with an ALK inhibitor: results from a phase 4 study

VIEW ABSTRACT

Please note this summary only contains information from the scientific abstract:

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Date of summary:
March 2025

Study number: NCT04362072

Study start date:
September 2020

Study end date:
October 2024

For more information on this study, go to:
https://clinicaltrials.gov/study/NCT04362072

KEY TAKEAWAY

What are the key takeaways from this study?

- The clinical trial showed that **lorlatinib** treatment was beneficial for people with *ALK*-positive NSCLC that got worse after their previous treatment
  - About 42% of people had their tumors shrink or disappear
  - For people whose cancer had spread to the brain prior to the start of the study, 47% had their tumors shrink or disappear
- Most people treated with **lorlatinib** had some side effects, but only a few people needed to decrease or stop their treatment because of these side effects

PHONETICS

Find out how to say medical terms used in this summary

ALK gene
< a-ell-kay jeen >

Lorlatinib
< lor-LA-tih-nib >

Metastatic
< meh-tuh-STA-tik >

GLOSSARY

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

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.

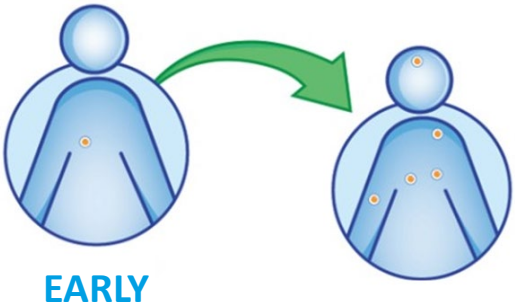
Metastatic/advanced: cancer that has spread from the place where it started to another part of the body.

Peripheral neuropathy: a nerve problem that causes pain, numbness, tingling, swelling, or muscle weakness in different parts of the body

What does this study look at?

What is advanced 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 metastatic or advanced NSCLC.



EARLY

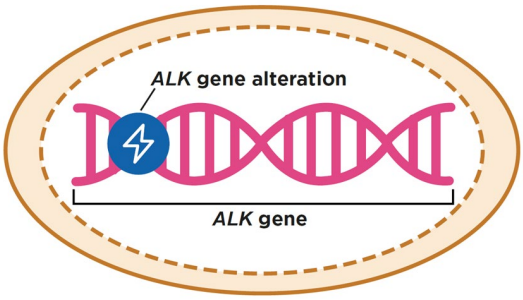
- Tumor starts in the lung

ADVANCED

- Tumor spreads to other parts of the body, which may include the brain

What is advanced *ALK*-positive NSCLC?

- Some people with NSCLC have changes in a gene called anaplastic lymphoma kinase or *ALK* in their cancer cells.
- The *ALK* gene makes a protein that 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 about 3% to 7% of 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 is lorlatinib?

- **Lorlatinib** is a type of medicine known as an ALK inhibitor. It is a third-generation ALK inhibitor, meaning that it is a newer type of ALK inhibitor. It stops cancer cells from growing and spreading by blocking the actions of proteins like ALK.

What is this study?

- In this study, researchers looked at the effects of an ALK inhibitor, **lorlatinib**, in people whose advanced lung cancer got worse after treatment with a second-generation ALK inhibitor.
- This was a single-arm open-label study, meaning that everyone received the same treatment, and both the researchers and the people participating in the study knew what treatment was being given.

Researchers wanted to find out…

- How well treatment with lorlatinib worked in people with advanced *ALK*-positive NSCLC whose disease had gotten worse after their previous second-generation ALK inhibitor treatment
- What the side effects of lorlatinib treatment were in this group of people

STUDY DETAILS

Who took part in this study?

- This study included people with advanced *ALK*-positive NSCLC whose disease got worse after their previous second-generation ALK inhibitor treatment.
- At total of 71 people took part in this study and were treated with **lorlatinib**.

People took part in the study and were treated with **lorlatinib** (third-generation ALK inhibitor)

60 people (85%) had previously received a medicine called alectinib (a second-generation ALK inhibitor)

11 people (15%) had previously received a medicine called ceritinib (a second-generation ALK inhibitor)

Half of the people in the study were treated with **lorlatinib** for

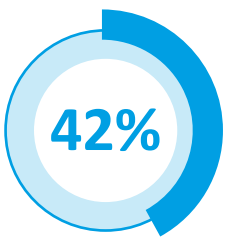
9.7 months

RESULTS

What were the efficacy results of this study?

How many people had their tumors shrink or disappear?

- 30 out of 71 people (42%) had their tumors shrink or disappear after starting **lorlatinib**



Among people who had their tumors shrink or disappear, how long did the effect last?

- Half of the people were studied for about 18.0 months after starting treatment
- **It was too early to tell** how long the effect will last because more than half of the people were still alive without their cancer getting worse
- There was a **65% chance** that people's tumors would respond (shrink or disappear) to **lorlatinib** for at least 12 months

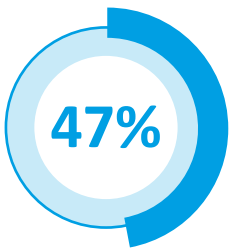
It was too early to tell because more than half of the people were still alive without their cancer getting worse

How long did half of the people in this study live without their cancer getting worse?

- For half of the people who took **lorlatinib**, their cancer did not get worse for estimated **12.2 months**
- There was a **51% chance** that their cancer would not get worse by 12 months

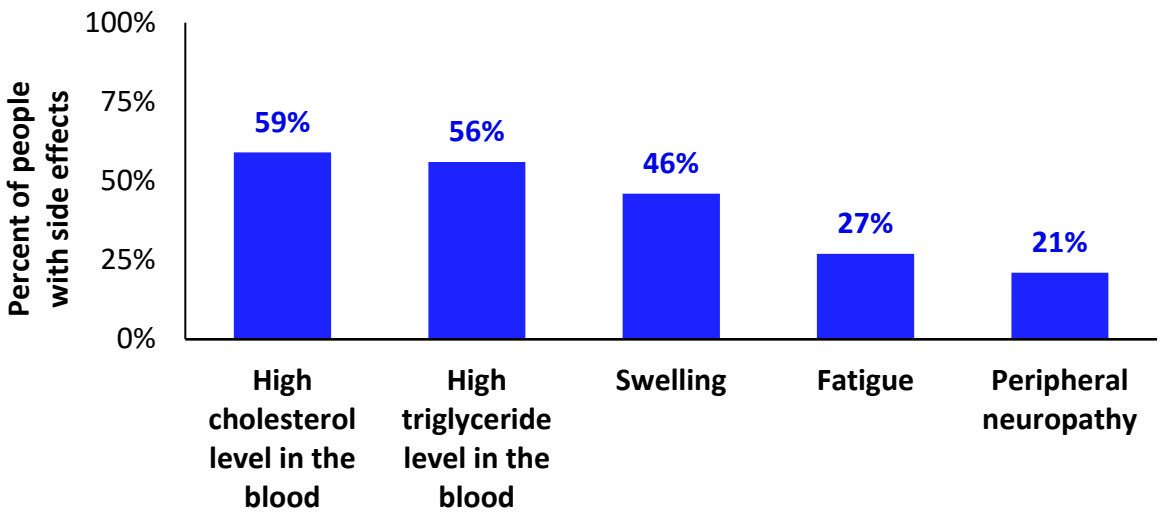
How many people whose cancer had spread to the brain had their tumors shrink or disappear?

- 30 out of 71 people had cancer that had spread to the brain prior to the start of the study
- 14 out of those 30 people (47%) had their tumors shrink or disappear after starting **lorlatinib**



What were the safety results of this study?

What were common side effects of taking lorlatinib?



How many people had to decrease or stop lorlatinib treatment because of side effects?

11 out of 71 people had to decrease **lorlatinib** dose

9 out of 71 people had to stop **lorlatinib**

None stopped **lorlatinib** because of side effects due to treatment

CONCLUSIONS

What were the main conclusions of this study?

- About 42% of people with advanced *ALK*-positive NSCLC who received **lorlatinib** had their tumors shrink or disappear
- For half of people treated with **lorlatinib**, their cancer did not get worse for 12.2 months
- For people whose cancer had spread to the brain prior to the start of the study, 47% had their tumors shrink or disappear with **lorlatinib** treatment
- Most people had side effects like high levels of cholesterol or triglycerides in the blood, swelling, fatigue, and peripheral neuropathy, but only a few people had to decrease or stop **lorlatinib** treatment

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. Lorlatinib is 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.

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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/NCT04362072

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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