ALK Positive Lung Cancer (UK)

TRIANA Clinical Trial

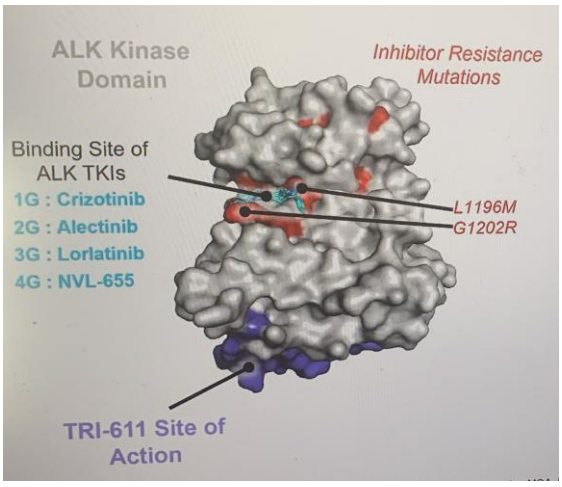
Trial ID: NCT07491497

Introduction

This leaflet is based on information that is available to the public. It explains the main points about the TRIANA trial. The rules about who can and cannot take part are detailed, so this leaflet may not cover every situation.

The trial is for people whose cancer is growing after treatment with targeted medicines called tyrosine kinase inhibitors (TKIs).

TRI-611 is a new medicine designed to break down the faulty ALK protein that drives this cancer. Current ALK medicines usually block this protein and TRI-611 is designed to work in a different way. Researchers hope it may work when current ALK medicines stop working, including when changes in the ALK protein make those medicines less effective. So far, this is based on laboratory studies. It is not yet known how well TRI-611 will work in people.



The trial opened in the USA in March 2026. The first part of the study is expected to include 160 people worldwide. This part will test different doses. A progress report on the trial is expected in 2029, and the full study is expected to finish in 2034.

What Is This Trial About?

The trial is testing a new, experimental medicine called TRI-611. It is taken by mouth as a tablet or capsule and is being studied in people with ALK-positive non-small cell lung cancer (NSCLC).

TRI-611 is designed to help the body break down the faulty ALK protein that causes this cancer.

This is an early-stage trial and is one of the first times TRI-611 has been tested in people. The trial is open label. This means that you and your doctors will know that you are taking TRI-611.

The trial aims to find out:

- how safe TRI-611 is and what side effects it causes
- which dose is best to use
- whether it can shrink the cancer or slow its growth

In Part 1, researchers will test different doses to find out how much medicine people can safely take. They will use the results to choose doses for further study.

After Part 1 is complete, Part 2 will have three groups: M1, M2 and M3. Which group people join will depend on the ALK medicines they have taken before. Researchers will study how well TRI-611 works against the cancer in these groups.

Who Can Take Part?

Your hospital team will check your medical history, scans and test results. This leaflet covers the main points, but the full list of rules is longer. Only the trial doctors can confirm whether you can take part.

You may be able to join if you:

- are aged 18 or over
- have cancer that can be measured on scans
- have bone marrow and organs that are working well enough for the trial
- have already taken certain ALK medicines called TKIs. The medicines you must have taken depend on which part of the trial you may join. See the next section for details.
- You may have had chemotherapy before.

You may not be able to join if:

- your cancer has other changes that are known to make TKIs less effective
- you have cancer that has spread to the central nervous system, or pressure on your spinal cord, and this is linked to worsening nerve or brain symptoms or means you need higher doses of steroid medicines to control the cancer
- you are still having treatment with another cancer medicine or a medicine being tested in a research study
- you are known to be allergic to TRI-611 or any of its ingredients
- you have had major surgery in the 4 weeks before your first dose of TRI-611

Which Part Of The Trial?

The treatments you have already had will help determine which part of the trial you may be able to join.

At first, only Part 1 will be open in the UK. Part 2 may open later. When it does, not all groups may be open. TRIANA Biomedicines will decide how many people can join each group. We do not yet know when each group will open or close.

PART 1

You must have had 2 or 3 TKIs, including Lorlatinib. Lorlatinib must not have been your first ALK treatment. One of the TKIs may be Neladalkib. Some chemotherapy may be allowed.

Example treatment histories:

- Alectinib or Brigatinib / Lorlatinib
- Crizotinib / Alectinib or Brigatinib / Lorlatinib
- Alectinib or Brigatinib / Lorlatinib / Neladalkib

PART 2

Cohort M1

You must have had 2 or 3 TKIs, including Lorlatinib. Lorlatinib must not have been your first ALK treatment. One of the TKIs must not be Neladalkib.

Example treatment histories:

- Alectinib or Brigatinib / Lorlatinib
- Crizotinib / Alectinib or Brigatinib / Lorlatinib

Cohort M2

You must have had 4 or more TKIs, including both Lorlatinib and Neladalkib. Neither medicine can have been your first ALK treatment.

Example treatment histories:

- Crizotinib / Alectinib or Brigatinib / Lorlatinib / Neladalkib
- Crizotinib / Ceritinib / Alectinib or Brigatinib / Lorlatinib / Neladalkib

Cohort M3

You must not have taken an ALK TKI before.

These are examples of treatment histories. Other treatment histories may also be allowed. Ask your oncologist or the trial team if you are unsure.

What Would Taking Part Involve?

- The trial hospital will explain the study so that you can decide whether to give consent.
- You will take TRI-611 by mouth. You will usually keep taking it for as long as you can tolerate it and your cancer is not getting worse.
- You will keep a diary of each time you take the medicine.
- You will have about 7 hospital visits in the first 3 months. After that, you will have one visit at the start of each 28-day treatment cycle.
- Visits will include tests, such as blood tests and scans.
- You can claim back reasonable costs for travelling to hospital visits.

Possible Benefits And Risks

TRI-611 is an experimental medicine. Researchers do not yet know all its possible side effects. The trial team will monitor you closely for side effects. The study doctors will explain the known and possible risks before you decide whether to take part.

Which UK Hospitals?

As of October 2026, we are aware that only The Royal Marsden Hospital in Sutton, London, is offering the trial in the UK. Please check with your oncologist or the trial team in case this changes.

Oncologists in the UK who want to refer a patient should email:

ddupa@rmh.nhs.uk

Next Steps And Contacts

- Talk to your oncologist about whether this trial may be suitable for you and whether they can refer you.
- Trial sponsor, TRIANA Biomedicines (general enquiries): medical@trianabio.com
- Trial information: https://clinicaltrials.gov/study/NCT07491497

Important Information

We have tried to make sure that this leaflet is accurate. However, do not use it on its own and nothing in this leaflet should stop you from asking your healthcare team about the trial.

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