



ALK Positive Lung Cancer (UK)

TRIANA Clinical Trial

A research study for adults with ALK-positive lung cancer

Trial ID: NCT07491497 · Sponsor: TRIANA Biomedicines

Introduction

This leaflet has been prepared by Alk Positive Lung Cancer (UK) from publicly available information. Inclusion and exclusion criteria can be complex and this leaflet does not attempt to cover all possible situations.

The trial is for patients whose cancer is growing following previous treatment with targeted therapies, Tyrosine Kinase Inhibitors (TKI).

In preclinical models, TRI-611 is a potent, highly selective, brain-penetrant, oral ALK fusion protein degrader that operates independently of the ALK binding site targeted by current tyrosine kinase inhibitors (TKIs). Because TRI-611 degrades the ALK fusion protein rather than simply inhibiting it, it may overcome or delay the resistance that commonly develops with current ALK TKIs. Based on preclinical data, this should occur even if prior ALK mutations have reduced TKI binding, because TRI-611 binds to a different part of the protein, and the protein is destroyed rather than inhibited. This may lead to deeper and more durable responses in patients with ALK-positive NSCLC.

The trial opened in the USA in March 2026 and it is expected that 160 patients world-wide will participate in Part 1 (dose escalation). Partial completion of the study is expected in 2029 and full completion in 2034.

What is this trial about?

This trial is testing a new, experimental medicine called TRI-611. It is a tablet or capsule taken by mouth, for ALK-positive non-small cell lung cancer (NSCLC). TRI-611 is a "molecular glue degrader", which is designed to help the body break down the faulty ALK protein that drives this cancer.

This is an early-stage (Phase 1/2) trial and one of the first times TRI-611 has been given to people. It is "open label", which means you and your doctors will know what you are taking.

The trial aims to find out:

- how safe TRI-611 is and what side effects it causes
- the best dose to use
- whether it shrinks or slows the cancer

Part 1 of the study consists of a dose escalation to determine the maximum tolerated dose and/or recommended dose(s) for further exploration.

Following completion of Part 1, the second part will comprise three cohorts (M1, M2, M3) of participants based on their previous treatment with TKIs. During this part of the study, the antitumor activity of TRI-611 will be further explored.

Who can take part?

Your hospital team will check your medical history, scans and test results. This leaflet gives the main points only, and the full list is longer. Only the trial doctors can confirm whether you are eligible.

You may be able to join if you:

- are 18 or over
- have cancer that can be measured on scans
- have adequate bone marrow reserve and organ function
- have already had certain TKIs, depending on which part of the trial you join (see below). Prior chemotherapy is allowed.

You may not be able to join if:

- your cancer has any additional driver alterations known to be a mechanism of resistance to TKIs
- you have central nervous system (CNS) metastases or spinal cord compression, they must not be associated with progressive neurological symptoms or require increasing doses of corticosteroids to control the CNS disease
- you are receiving ongoing treatment with another anticancer treatment or investigational agent
- there is known allergy/hypersensitivity to TRI-611 or any of its ingredients
- you have had major surgery within 4 weeks of receiving the first dose of TRI-611

Which part of the trial?

Which group you could join depends on the treatments you have already had.

Initially, only Part 1 of the trial will be open in the UK. When Part 2 opens, not all cohorts may be open and Triana Biomedicines will determine the number of patients in each cohort. The time cohorts open and close is unpredictable at this time.

- **Part 1:** you will have had 2 or 3 TKIs, including Lorlatinib, which must not have been your very first ALK treatment. One of the TKIs could be Neladalkib. Some chemotherapy may be allowed.

Example pathways

Alectinib or Brigatinib/Lorlatinib

Crizotinib/Alectinib or Brigatinib/Lorlatinib

Alectinib or Brigatinib/Lorlatinib/Neladalkib

- **Cohort M1:** you will have had 2 or 3 TKIs, including Lorlatinib, which must not have been your very first ALK treatment. One of the TKIs could not be Neladalkib.

Example pathways

Alectinib or Brigatinib/Lorlatinib

Crizotinib/Alectinib or Brigatinib/Lorlatinib

- **Cohort M2:** you will have had 4 or more TKIs, including both Lorlatinib and Neladalkib, neither as your first ALK treatment.

Example pathways

Crizotinib/Alectinib or Brigatinib/Lorlatinib/Neladalkib

Crizotinib/Ceritinib/Alectinib or Brigatinib/Lorlatinib/Neladalkib

- **Cohort M3:** you will not have had any ALK TKI before.

The example pathways are not exclusive.

What would taking part involve?

- The Trial hospital will provide full information about the trial so that you can give consent
- You will take TRI-611 by mouth, usually for as long as it is well tolerated and your cancer is not getting worse.
- You keep a diary of each time you take it.
- About 7 clinic visits in the first 3 months, then one visit at the start of each 28-day cycle.
- Visits will include tests such as blood tests and scans.
- Reasonable expenses in making hospital visits will be reimbursed.

Possible benefits and risks

TRI-611 is experimental, so its full side effects are not yet known. You will be closely monitored, and you might have side effects. The study doctors will explain the known and possible risks.

Which UK hospitals?

Currently (Oct 2026), we are aware that only The Royal Marsden Hospital, Sutton, London, is offering the trial in the UK.

Oncologists throughout the UK who wish to refer their patients should email ddupa@rmh.nhs.uk

Next steps and contacts

- Talk to your oncologist about whether this trial might suit you and whether they can refer you.
- Trial sponsor - TRIANA Biomedicines (general enquiries): medical@trianabio.com
- Trial Information - <https://clinicaltrials.gov/study/NCT07491497>

Disclaimer

Whilst we try to ensure information in this leaflet is accurate, patients should not rely on any information in the leaflet when making any decisions about their treatment. They must act only on the advice of their healthcare teams.

In particular, patients should not, as a result of reading the leaflet, be deterred from asking their healthcare providers about the trial.

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