

ALINA: efficacy and safety of adjuvant alectinib versus chemotherapy in patients with early-stage ALK+ NSCLC

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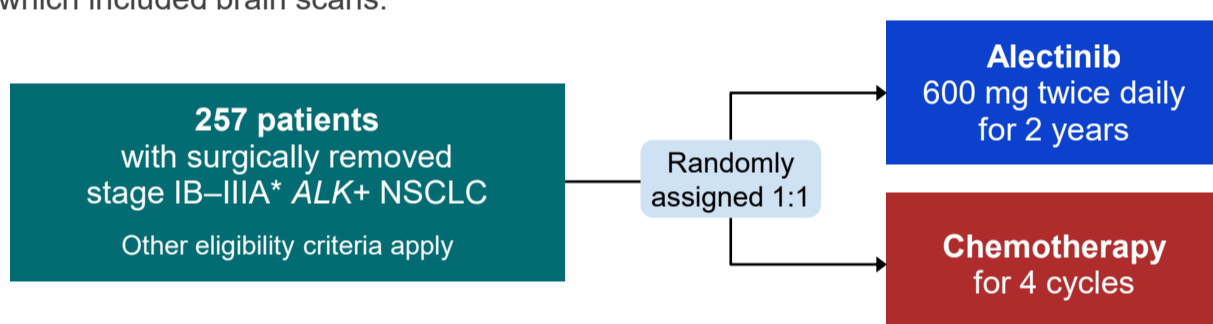
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Why was the ALINA study done?

- **ALK-positive NSCLC** is caused by an abnormality in the *ALK* gene that causes cancer cells to become overactive, and to grow and divide uncontrollably.
- For patients with **ALK-positive NSCLC** that can be removed by surgery (known as 'resectable' disease), the current recommended treatment is surgery followed by chemotherapy.¹ However, the risk of the cancer returning after surgery and chemotherapy remains high.²
- **Alectinib** is a medicine that blocks the activity of the abnormal ALK protein, reducing or preventing cancer growth. For patients with later stages of ALK-positive NSCLC, where the cancer has spread to other parts of the body, alectinib is known to be highly effective and is already a recommended treatment.^{1,3-5}
- **The ALINA study** assessed whether giving alectinib to patients with resectable ALK-positive NSCLC after surgery could reduce the risk of cancer coming back.
- The primary aim was to assess if alectinib after surgery was superior to chemotherapy after surgery for patients with resectable ALK-positive NSCLC. This was done by measuring how long patients remained alive without their cancer returning (known as '**disease-free survival**').
- Other aims of the study included whether alectinib can reduce the risk of **cancer recurrence in the brain**, how long patients lived (known as 'overall survival'), and **safety**.

How was the study done?

- After surgery to remove the tumour, patients with resected ALK-positive stage IB–IIIA NSCLC were randomly assigned to receive either alectinib or chemotherapy.
- All patients were closely followed throughout the study with regular disease assessments, which included brain scans.



What were the findings of this research?

- At the time of this analysis, patients had been part of the study for an average of 28 months.
- The primary aim of the study was met: patients who received alectinib had **76% less risk of their cancer coming back** than those who received chemotherapy.
- The proportion of patients who were alive and cancer-free at two years was 94% with alectinib versus 64% with chemotherapy.
- Alectinib improved disease-free survival across all patient groups, including for people with different disease stage, race, sex, and smoking history.
- Fewer patients in the alectinib group had cancer spread to the brain (four versus 14). Alectinib reduced the risk of cancer recurrence in the brain or death compared with chemotherapy.
- At the time of this analysis, too few patients had died (2.3%) to measure a statistical difference in overall survival between alectinib and chemotherapy.[†]
- No new safety concerns were identified for alectinib, and few people stopped treatment due to side effects (5% with alectinib versus 13% with chemotherapy).

What do these findings mean?

- For patients with ALK-positive NSCLC, **treatment with alectinib after surgery significantly reduced the chance of cancer returning** or death compared with chemotherapy
- These data support testing for changes in the *ALK* gene for patients with all stages of NSCLC.

What other trials of alectinib are being done?

HORIZON-1
International
NCT05170204

Phase III study that includes a group of patients with stage III, ALK+ NSCLC that cannot be removed by surgery, who receive chemoradiotherapy and then either alectinib or durvalumab⁶

NAUTIKA-1
USA
NCT04302025

Phase II study that includes a group of patients with resectable stage IB–IIIA ALK+ NSCLC who receive alectinib, surgery, chemotherapy, and then further treatment with alectinib⁷

ALNEO
Italy
NCT05015010

Phase II study of alectinib before and after surgery in patients with resectable stage III, ALK+ NSCLC⁸

Where can I access more information?

- More information about the ALINA study can be found on ClinicalTrials.gov (NCT03456076): <https://www.clinicaltrials.gov/study/NCT03456076>
- Download the **ESMO 2023 presentation** of the ALINA study results for more details: <https://ter.li/bv1tv1>