A Study Comparing Alectinib With Crizotinib in Treatment-Naive Anaplastic Lymphoma Kinase-Positive Advanced Non-Small Cell Lung Cancer Participants (ALEX)

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	325
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Tiene resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-506859-13-00 (CTIS)

Cod. Protocolo
BO28984

Transicionado 2013-004133-33

Área terapéutica
Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada
Anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC)

Título Científico
Randomized, Multicenter, Phase III, Open-Label Study of Alectinib Versus Crizotinib In Treatment-Naive Anaplastic Lymphoma Kinase-Positive Advanced Non-Small Cell Lung Cancer

Justificación

No aportado

Objetivo Principal

To evaluate and compare the efficacy of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC), as measured by investigator-assessed progression-free survival (PFS)

Variables de Evaluación Primaria

1. PFS, as assessed by investigator

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate and compare the ORR and duration of response (DOR) of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer by investigator
To evaluate and compare the time to progression in the CNS of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer on the basis of Independent Review Committee (IRC) review of radiographs by RECIST v1.1 and Revised Assessment in Neuro Oncology (RANO) criteria, as well as: To evaluate CNS ORR (C-ORR) in patients with CNS metastases who have measurable disease in the CNS at baseline To assess CNS DOR (C-DOR) in patients who have a CNS OR To assess CNS progression rates (C-PR) at 6, 12, 18, and 24 months on the basis of cumulative incidence
To evaluate and compare the PFS assessment by the IRC of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer
To evaluate and compare the OS of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer
To evaluate the safety and tolerability of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer
To characterize the pharmacokinetics of alectinib and metabolite(s) in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer
To evaluate and compare time to deterioration (TTD) of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer in patient-reported lung cancer symptoms
To evaluate and compare PROs of health-related quality of life (HRQoL), patient functioning, and side effects of treatment of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer

Variables de Evaluación Secundaria

1. PFS by IRC
2. Time to CNS Progression by IRC
3. ORR as determined by the investigators using RECIST v1.1.
4. DOR
5. Time to deterioration (TTD) in patient-reported lung cancer symptoms
6. Health-related quality of life (HRQoL)
7. Safety and tolerability
8. Pharmacokinetics of alectinib and metabolite(s)
9. Overall survival (OS)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Histologically or cytologically confirmed diagnosis of advanced or recurrent (Stage IIIB not amenable for multimodality treatment) or metastatic (Stage IV) NSCLC that is ALK-positive as assessed by the Ventana immunohistochemistry (IHC) test. Sufficient tumor tissue to perform ALK IHC and ALK fluorescent in situ hybridization (FISH) is required. Both tests will be performed at designated central laboratories.
Measurable disease (by Response Evaluation Criteria In Solid Tumors [RECIST] v1.1) prior to the administration of study treatment
Patients had no prior systemic treatment for advanced or recurrent (Stage IIIB not amenable for multimodality treatment) or metastatic (Stage IV) NSCLC.
Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) of 0-2
Adequate hematologic, renal and liver function.
Prior brain or leptomeningeal metastases allowed if asymptomatic (e.g., diagnosed incidentally at study baseline). Asymptomatic CNS lesions might be treated at the discretion of the investigator as per local clinical practice. If patients have neurological symptoms or signs due to CNS metastasis, patients need to complete whole brain radiation or gamma knife irradiation treatment. In all cases, radiation treatment must be completed at least 14 days before enrollment and patients must be clinically stable.

Criterios de Exclusión

Patients with a previous malignancy within the past 3 years are excluded (other than curatively treated basal cell carcinoma of the skin, early gastrointestinal (GI) cancer by endoscopic resection, in situ carcinoma of the cervix, or any cured cancer that is considered to have no impact in PFS and OS for the current NSCLC). Any gastrointestinal (GI) disorder that may affect absorption of oral medications, such as mal absorption syndrome or status post-major bowel resection National Cancer Institute Common Terminology Criteria for Adverse Events (version 4.0) Grade 3 or higher toxicities due to any prior therapy such as radiotherapy (excluding alopecia), which have not shown improvement and are strictly considered to interfere with current study medication Liver disease - ALT or AST > 3 x upper limit of normal OR - Impaired excretory function OR - Acute viral or active autoimmune alcoholic, or other types of acute hepatitis Patients with baseline QTc > 470 ms or symptomatic bradycardia Administration of strong/potent cytochrome P4503A inhibitors or inducers within 14 days prior to the first dose of study treatment and while on treatment with alectinib or crizotinib. Administration of agents with potential QT interval prolonging effects within 14 days prior to the first administration of study drug for all patients and while on treatment through the end of the study for crizotinib-treated patients only

Calendario

(Última actualización: 06/02/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
26/01/2015	20/03/2015	12/05/2015	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
20/01/2016	No aportado	No aportado	09/12/2024	09/04/2025

Promotor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitari Vall d Hebron

Passeig de la Vall d.Hebron, 119-129 - Edificio Materno-Infantil, planta 13 08035 Barcelona

ceic@vhir.org

934894010

Centros

Cerrado (26/07/2022)

COMPLEJO HOSPITALARIO REGIONAL VIRGEN DEL ROCÍO

SEVILLA

SEVILLA

Cerrado (13/06/2016)

COMPLEJO HOSPITALARIO UNIVERSITARIO INSULAR-MATERNO INFANTIL

PALMAS DE GRAN CANARIA (LAS)

LAS PALMAS

Cerrado (29/04/2016)

COMPLEJO UNIVERSITARIO LA PAZ

MADRID

MADRID

Cerrado (17/02/2017)

HOSPITAL UNIVERSITARI QUIRÓN DEXEUS

BARCELONA

BARCELONA

Cerrado (07/04/2016)

HOSPITAL CLÍNIC I PROVINCIAL DE BARCELONA

BARCELONA

BARCELONA

Cerrado (09/05/2016)

HOSPITAL CLÍNICO UNIVERSITARIO LOZANO BLESA

ZARAGOZA

ZARAGOZA

Cerrado (08/02/2019)

HOSPITAL GENERAL UNIVERSITARIO DE ALICANTE

ALICANTE/ALACANT

MURCIA

Cerrado (11/05/2016)

HOSPITAL RAMÓN Y CAJAL

MADRID

MADRID

Cerrado (29/07/2022)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

BADALONA

BARCELONA

Cerrado (15/07/2022)

HOSPITAL UNIVERSITARI VALL D'HEBRON

BARCELONA

BARCELONA

Cerrado (11/05/2016)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

MADRID

MADRID

Cerrado (27/01/2026)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

MAJADAHONDA

MADRID

Cerrado (05/05/2016)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

MADRID

MADRID

Medicamentos

Alectinib (Alecensa)
CAPSULE, HARD
ORAL

-

Principios Activos: N/A

Experimental

Alecensa 150 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L01ED03 - ALECTINIB
Principios Activos: N/A

Experimental

XALKORI 200 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L01ED01 - CRIZOTINIB
Principios Activos: N/A

Experimental

XALKORI 250 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L01ED01 - CRIZOTINIB
Principios Activos: N/A

Experimental

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CAPSULE, HARD
ORAL

Código ATC: L01ED01 - CRIZOTINIB
Principios Activos: N/A

Experimental

XALKORI 250 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L01ED01 - CRIZOTINIB
Principios Activos: N/A

Experimental

Tiene resultados

A Study Comparing Alectinib With Crizotinib in Treatment-Naive Anaplastic Lymphoma Kinase-Positive Advanced Non-Small Cell Lung Cancer Participants (ALEX)

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	325
Results	**Low level of intervention**	**Rare disease**
Has results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-506859-13-00 (CTIS)

Protocol Code
BO28984

Transitioned 2013-004133-33

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC)

Scientific Title
Randomized, Multicenter, Phase III, Open-Label Study of Alectinib Versus Crizotinib In Treatment-Naive Anaplastic Lymphoma Kinase-Positive Advanced Non-Small Cell Lung Cancer

Rationale

Not provided

Main Objective

To evaluate and compare the efficacy of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC), as measured by investigator-assessed progression-free survival (PFS)

Primary Endpoints

1. PFS, as assessed by investigator

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate and compare the ORR and duration of response (DOR) of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer by investigator
To evaluate and compare the time to progression in the CNS of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer on the basis of Independent Review Committee (IRC) review of radiographs by RECIST v1.1 and Revised Assessment in Neuro Oncology (RANO) criteria, as well as: To evaluate CNS ORR (C-ORR) in patients with CNS metastases who have measurable disease in the CNS at baseline To assess CNS DOR (C-DOR) in patients who have a CNS OR To assess CNS progression rates (C-PR) at 6, 12, 18, and 24 months on the basis of cumulative incidence
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To evaluate and compare PROs of health-related quality of life (HRQoL), patient functioning, and side effects of treatment of alectinib compared with crizotinib in patients with treatment-naive anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer

Secondary Endpoints

1. PFS by IRC
2. Time to CNS Progression by IRC
3. ORR as determined by the investigators using RECIST v1.1.
4. DOR
5. Time to deterioration (TTD) in patient-reported lung cancer symptoms
6. Health-related quality of life (HRQoL)
7. Safety and tolerability
8. Pharmacokinetics of alectinib and metabolite(s)
9. Overall survival (OS)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Histologically or cytologically confirmed diagnosis of advanced or recurrent (Stage IIIB not amenable for multimodality treatment) or metastatic (Stage IV) NSCLC that is ALK-positive as assessed by the Ventana immunohistochemistry (IHC) test. Sufficient tumor tissue to perform ALK IHC and ALK fluorescent in situ hybridization (FISH) is required. Both tests will be performed at designated central laboratories.
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Calendar

(Last Update: 06/02/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
26/01/2015	20/03/2015	12/05/2015	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
20/01/2016	Not aported	Not aported	09/12/2024	09/04/2025

Sponsor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari Vall d Hebron

Passeig de la Vall d.Hebron, 119-129 - Edificio Materno-Infantil, planta 13 08035 Barcelona

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Sites

Closed (26/07/2022)

COMPLEJO HOSPITALARIO REGIONAL VIRGEN DEL ROCÍO

SEVILLA

SEVILLA

Closed (13/06/2016)

COMPLEJO HOSPITALARIO UNIVERSITARIO INSULAR-MATERNO INFANTIL

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Closed (29/04/2016)

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Closed (09/05/2016)

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Closed (08/02/2019)

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Closed (11/05/2016)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

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Closed (27/01/2026)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

MAJADAHONDA

MADRID

Closed (05/05/2016)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

MADRID

MADRID

Medication

Alectinib (Alecensa)
CAPSULE, HARD
ORAL

-

Active Principles: N/A

Experimental

Alecensa 150 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L01ED03 - ALECTINIB
Active Principles: N/A

Experimental

XALKORI 200 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L01ED01 - CRIZOTINIB
Active Principles: N/A

Experimental

XALKORI 250 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L01ED01 - CRIZOTINIB
Active Principles: N/A

Experimental

XALKORI 200 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L01ED01 - CRIZOTINIB
Active Principles: N/A

Experimental

XALKORI 250 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L01ED01 - CRIZOTINIB
Active Principles: N/A

Experimental

Has results