LUNG Study

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Main Information

Primary registry identifying number
LBCTR2024015481

Protocol number
ML44926

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
06/12/2023

Primary sponsor
Hôtel-Dieu de France University Hospital

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
29/10/2024

Date of registration in national regulatory agency
06/12/2023

Public title
LUNG Study

Acronym

Scientific title
A Biomarker-Driven Precision Management of Lebanese Patients with Previously Untreated Metastatic Non-Squamous Non-Small Cell LunG Cancer

Acronym

Brief summary of the study: English

A Biomarker-Driven Precision Management of Lebanese Patients with Previously Untreated Metastatic Non-Squamous Non-Small Cell LunG Cancer – LUNG study
Protocol number: ML44926
Lung cancer is the most common cancer worldwide and is still responsible for most cancer deaths. In Lebanon, more than 1000 cases of lung cancer are diagnosed each year. The Lebanese National Cancer Registry showed that Lebanon has the highest incidence of lung cancer in females and the second highest for males in the MENA region. The high cigarette and water-pipe consumption rate among the Lebanese population plays a key role, in addition to several other risk factors. For decades, cytotoxic chemotherapy has been the cornerstone of management of metastatic non- squamous non-small cell lung cancer (NS-NSCLC). The recognition of specific somatic ‘driver’ mutations in NSCLC has transformed both the treatment and outcomes for patients with advanced-stage lung cancer. The current two-step study will report on the prevalence of a plethora of tumor biomarkers (screening period). A specific set of activating mutations will characterize patients who will be offered participation in the treatment phase of the study, a parallel-arm umbrella trial that will assess the efficacy and safety of two orally administered precision medicine treatments (alectinib and entrectinib).

Brief summary of the study: Arabic

إعتماد الطّب الدقيق بحسب الواصمات الحيوية لمعالجة سرطان الرئة غير صغير الخلايا المنتشر الذي لم يتمّ علاجه سابقًا لدى المرضى اللبنانيين – دراسة LUNG
البروتوكول رقم: ML44926
يُعدّ سرطان الرئة أكثر أنواع السرطان شيوعًا في جميع أنحاء العالم ولا يزال مسؤولاً عن معظم الوفيات الناجمة عن السرطان. في لبنان، يتمّ تشخيص أكثر من ١٠٠٠ حالة سرطان الرئة كل عام. أظهر السجل الوطني اللبناني للسرطان أن لبنان يسجّل أعلى معدّل للإصابة بسرطان الرئة بين الإناث وثاني أعلى معدل بين الذكور في منطقة الشرق الأوسط وشمال أفريقيا. ويلعب إرتفاع معدّل إستهلاك السجائر والشيشة بين اللبنانيين دوراً رئيسياً، بالإضافة إلى العديد من عوامل الخطر الأخرى.
لطالما كان العلاج الكيميائي هو أساس علاج سرطان الرئة ذو الخلايا غير الحرشفية غير الصغيرة النقيلي. أدّى اكتشاف بعض الوصمات الحيويّة المحدّدة في سرطان الرئة غير صغير الخلايا إلى تغيير كل من العلاج والنتائج للمرضى الذين يعانون من سرطان الرئة في مرحلة متقدمة. ستقدّم الدراسة الحالية المكوّنة من خطوتين تقريرًا عن مدى انتشار عدد كبير من الوصمات الحيويّة للورم (فترة فحص الوصمات الحيويّة). أمّا المرضى ذوو الورم الذي يحتوي على وصمات حيويّة محدّدة في هذه الدراسة فسيُعرض عليهم المشاركة في مرحلة العلاج من الدراسة، وهو بحث من شأنه تقييم فعالية وسلامة إثنين من علاجات الطب الدقيق التي يتمّ تناولها عن طريق الفم (الألكتينيب والإنتركتينيب).

Health conditions/problem studied: Specify

Metastatic non-squamous non-small cell lung cancer

Interventions: Specify

Alectinib and Entrectinib

Key inclusion and exclusion criteria: Inclusion criteria

The patient must meet all the following criteria to be enrolled in the study:
1. The patient is ≥ 18 years of age.
2. The patient has signed the ICF.
3. Diagnosis of pathologically confirmed metastatic NS-NSCLC, for which no treatment has yet been administered (i.e. newly diagnosed metastatic NS-NSCLC).
4. Measurable NS-NSCLC metastatic lesions.
5. Karnofsky performance status ≥ 60 or ECOG performance status 0-2.
6. If patient has brain metastasis, they must have been stable for at least 4 weeks.
7. The patient is willing to and capable of taking the study drug by mouth.
8. Women of childbearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

100

Key inclusion and exclusion criteria: Exclusion criteria

Patients meeting any of the following exclusion criteria must not be enrolled in the study:
1. The patient has received prior investigational therapy, chemotherapy, surgery, or radiotherapy within 4 weeks of initiating study drug.
2. The patient has a significant medical history or unstable medical condition (unstable systemic disease: congestive heart failure (New York Heart Association Functional Classification class II or worse), recent myocardial infarction within 3 months, unstable angina, uncontrolled seizure disorder, uncontrolled hypertension). Patients with controlled diabetes (at the physician's discretion) will be allowed.
3. The patient is pregnant (confirmed by serum Beta-HCG if applicable), is breastfeeding or is not using adequate contraception (for patients of child-bearing potential).
4. The patient is actively taking herbal remedies or over-the-counter biologics (e.g., shark cartilage, high dose antioxidants).
5. The patient from a given study arm has already received the same therapy as the clinical trial.
The eligibility criteria have been broadened to allow more patients to benefit from the biomarker screening phase of the LUNG trial. However, patients who are determined to harbor an actionable mutation within the scope of this study will be further evaluated to determine whether they are candidates for the treatment, at the discretion of the investigator. The investigator might assess the patients for hematologic

function, hepatic function, renal function, and other parameters, before allowing them to join the treatment phase of this trial.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Non-randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

Active

Study phase

2 to 3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

Europe, USA, Lebanon

Name of IMP

Alectinib and Entrectinib

Year of authorization

2017

Month of authorization

11

Type of IMP

Others

Pharmaceutical class

Tyrosine kinase inhibitor

Therapeutic indication

first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC) who express biomarkers of interest, targeted by alectinib or entrectinib.

Therapeutic benefit

It is expected, based on promising clinical trials, that the precision therapies will improve prognosis and prolong survival

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples with DNA**

Biospecimen description

Archived biopsies or recently obtained biopsies from the lung tumor will be sent to the Jacques Loiselet Center for Medical Genetics and Genomics at the Saint Joseph University in Beirut. This laboratory will determine the presence of biomarkers in tumor samples, using the AVENIO Tumor Tissue CGP Kit for genomic testing of solid tumors

Target sample size

162

Actual enrollment target size

202

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

02/01/2024

Date of study closure: Type

Anticipated

Date of study closure: Date

31/03/2026

Recruitment status

Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan

No

IPD sharing statement description

Patients will not be identified by their names or date of birth on the case report form or other study documentation submitted to the sponsor; instead patients will be given a unique identification number as soon as they have signed the informed consent form (ICF). For safety reasons, the investigators will maintain a 'patient identification log' with the name and contact details of each patient. This log and the signed ICFs will be kept in strict confidence by the investigators

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
NA	NA

Sources of Monetary or Material Support

Name
Roche Lebanon

Secondary Sponsors

Name
Hotel Dieu de France

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Virginia El Khoury	Hotel Dieu de France	Lebanon	00961 1 604 000	felkarak@yahoo.com	Principle Investigator
Scientific	Fadi ElKarak	Hotel Dieu de France	Lebanon	009611421229	virginia.elkhoury@usj.edu.lb	Secretary of the Ethics Committee

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu de France	Dr. Fadi El Karak	Oncologist	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	06/01/2024	Michel Scheuer	cue@usj.edu.lb	009611421229

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Lung cancer	Carcinoma in situ of other specified sites (D09.7)	Metastatic Non-squamous non-small cell lung cancer

Interventions

Intervention	Description	Keyword
Alectinib	Total daily dose of 1200 mg: 600 mg (4 tablets) taken twice daily Must be taken with food	150 mg
entrectininb	Total daily dose of 600 mg (3 tablets) taken once daily Taken with or without food Should not be taken with grapefruit or grapefruit juice	200 mg

Primary Outcomes

Name	Time Points	Measure
Proportion of oncogenic driver mutations of interest: ALK rearrangement, NTRK gene fusion, MET alteration (skip mutation at Exon 14), EGFR mutation, ROS1 gene fusion, RET gene fusion, HER-2 (ERBB2) mutations, BRAF mutations, and potentially other biomarkers	cross-sectional, one-time assessment	proportion, counts and measures
Proportion of patients in the different oncogenic driver mutation percent brackets	cross-sectional, one-time assessment	proportion, counts and measures
Proportion of patients with non-activating mutations	cross-sectional, one-time assessment	proportion, counts and measures
Proportion of patients whose treatment will be based on the molecular biomarker profile	cross-sectional, one-time assessment	proportion, counts and measures

Key Secondary Outcomes

Name	Time Points	Measure
Proportion of patients achieving CR (disappearance of all target lesions), PR (≥30% decrease in the sum of the longest diameter of target lesions) and OR = CR + PR; according to RECIST v1.1 (23, 24) for target lesions and assessed by imaging at 3 months, 6 months and 12 months after treatment initiation	3, 6 and 12 months after treatment initiation	proportion, counts and measures
Proportion of patients with SD, at 3, 6 and 12 months after treatment initiation	3, 6 and 12 months after treatment initiation	proportion, counts and measures
Proportion of patients with PD at 3 months, 6 months and 12 months after treatment initiation	3, 6 and 12 months after treatment initiation	proportion, counts and measures
PFS estimated by the Kaplan-Meier method	3, 6 and 12 months after treatment initiation	duration
Description of AEs and ADRs reported during the study	3, 6 and 12 months after treatment initiation	counts and percentages
Proportion of patients who discontinued treatment due to safety concerns	3, 6 and 12 months after treatment initiation	proportion, counts and measures
Time to treatment discontinuation	3, 6 and 12 months after treatment initiation	duration

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files