Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A phase III, non-inferiority clinical trial to compare efficacy and safety of Pembrolizumab (produced by CinnaGen Co.) versus Pembrolizumab (Keytruda®, produced by Merck Company) in metastatic Non-Small Cell Lung Cancer (NSCLC) patients

Protocol summary

Study aim
Compare efficacy and safety of Pembrolizumab (CinnaGen Co.) versus Pembrolizumab (Keytruda®, Merck Company) in metastatic Non-Small Cell Lung Cancer (NSCLC) patients.

Design
A Phase III, randomized, two armed, double-blind, multi-center, parallel, active controlled, non-inferioirity

Settings and conduct
Phase III, randomized, two armed, double-blind, parallel, active controlled, non-inferiority clinical trial with 2:1 allocation and sample size 295, in 14 cities of Iran. Patients will receive 200 mg pembrolizumab (CinnaGen) or Keytruda® every 3 weeks IV for 51 weeks in addition to concurrent chemotherapy regimen (based on cancer histology), both vials of pembrolizumab (CinnaGen Co.) and Keytruda® (Merck Company) used in the study were unrecognizable to the patients and the relevant medical staff because they were completely similar in terms of shape, size, material and color and it is not possible to distinguish the type of drugs from their appearance.

Participants/Inclusion and exclusion criteria
Inclusion confirmed diagnosis of metastatic NSCLC, measurable disease, life expectancy≥3 months, (ECOG) ≤1, PD-L1 status evaluation possibility Exclusion systemic therapy for treatment of metastatic NSCLC, receiving systemic steroid therapy≤3 days prior to the first dose of trial, expected to require any other form of systemic or localized antineoplastic therapy; received thoracic radiation therapy of>30 Gy within 6 months, Untreated CNS metastases and, or carcinomatous meningitis, Active autoimmune disease, allogeneic tissue, solid organ transplant, interstitial lung disease OR history of pneumonitis, active infection, known sensitivity to pembrolizumab or chemotherapy regimen, pre-existing Grade ≥ 2 peripheral neuropathy

Intervention groups
1: 200 mg pembrolizumab + approved combination chemotherapy 2: 200 mg Keytruda + approved combination chemotherapy

Main outcome variables
PFS

General information

Reason for update
According to the amendment announced by the sponsor (CinnaGen Company) dated 05/28/1402 and the final approval announcement from the Food and Drug Organization dated 05/30/1402, changes were made.

Acronym

IRCT registration information
IRCT registration number: **IRCT20150303021315N29**
Registration date: **2022-04-03, 1401/01/14**
Registration timing: **prospective**

Last update: **2023-08-28, 1402/06/06**
Update count: **2**

Registration date
2022-04-03, 1401/01/14

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-04-12, 1401/01/23

Expected recruitment end date
2025-04-12, 1404/01/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A phase III, non-inferiority clinical trial to compare efficacy and safety of Pembrolizumab (produced by CinnaGen Co.) versus Pembrolizumab (Keytruda®, produced by Merck Company) in metastatic Non-Small Cell Lung Cancer (NSCLC) patients

Public title
Non-inferiority clinical trial to compare efficacy and safety of Pembrolizumab (CinnaGen Co.) versus Keytruda® in patients with metastatic Non-Small Cell Lung Cancer (NSCLC)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged 18-75 years old at the time of signing informed consent form 2. Have a histologically or cytologically confirmed diagnosis of NSCLC, is stage IV, does not have an EGFR sensitizing (activating) mutation or ALK translocation or ROS1 rearrangement Have measurable disease based on RECIST 1.1 as determined by the site Have a life expectancy of at least 3 months ECOG Performance Status 0 or 1 Have adequate organ and marrow function Subject has no history of prior malignancy, with the exception of basal cell carcinoma of the skin, superficial bladder cancer, squamous cell carcinoma of the skin, in situ cervical cancer, or has undergone potentially curative therapy with no evidence of that disease recurrence for 5 years since initiation of that therapy Have provided a formalin fixed tumor tissue sample from a biopsy of a tumor lesion either at the time of or after the diagnosis of metastatic disease has been made AND from a site not previously irradiated to assess for PD-L1 status. Fine needle aspirates, Endobronchial Ultrasound (EBUS) or cell blocks are not acceptable. Needle or excisional biopsies, or resected tissue is required.

Exclusion criteria:
Has received systemic therapy for the treatment of their stage IV NSCLC. Completion of treatment with chemotherapy and/or radiation as part of neoadjuvant/adjuvant therapy is allowed as long as therapy was completed at least 6 months prior to the diagnosis of metastatic disease Is currently participating and receiving study therapy or has participated in a study of an investigational agent and received study therapy or used an investigation device within 4 weeks of the first dose of treatment Is receiving systemic steroid therapy ≤ 3 days prior to the first dose of trial treatment or receiving any other form of immunosuppressive medication • corticosteroid use on study for management of ECIs, as pre-medication for the control chemotherapies, and/or a premedication for IV contrast allergies/reactions is allowed • Subjects who are receiving daily steroid replacement therapy serve as an exception to this rule. Daily prednisone at doses of 5-7.5 mg is an example of replacement therapy. Equivalent hydrocortisone doses are also permitted if administered as a replacement therapy. • The daily oral administration of 8 milligrams of dexamethasone during visits with concurrent chemotherapy is permitted to prevent chemotherapy-induced nausea and vomiting and pemetrexed-induced cutaneous adverse effects. Is expected to require any other form of systemic or localized antineoplastic therapy while on trial (including maintenance therapy with another agent for NSCLC, radiation therapy, and/or surgical resection) Major surgery within 3 weeks of the first dose of trial treatment; received thoracic radiation therapy of > 30 Gy within 6 months of the first dose of trial treatment Has received prior therapy with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody Has untreated central nervous system (CNS) metastases and/or carcinomatous meningitis identified either on the baseline brain imaging obtained during the screening period OR identified prior to signing the ICF o Subjects with previously treated brain metastases may participate provided they are clinically stable (neurologically asymptomatic) and have no evidence of new or enlarging brain metastasis by imaging at least 2 weeks after treatment of the brain metastases (e.g., surgery, RT) and are off steroids for at least 3 days prior to the first dose of study medication Active autoimmune disease that has required systemic treatment in past 2 years (i.e. with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (i.e., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment. Subjects that require inhaled corticosteroids would not be excluded from the study Has had an allogeneic tissue/solid organ transplant Has interstitial lung disease (ILD) OR has had a history of pneumonitis that has required oral or IV steroids Has received or will receive a live vaccine within 30 days prior to the first administration of study medication. Seasonal flu vaccines that do not contain a live virus are permitted Has an active infection Has known Human Immunodeficiency Virus (HIV) (HIV 1/2 antibodies) Has known Hepatitis B or Hepatitis C Has a history or current evidence of any condition, therapy, or laboratory abnormality that might confound the results of the trial, interfere with the subject's participation for the full duration of the trial, or is not in the best interest of the subject to participate, in the opinion of the treating Investigator Has known psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the trial. Is, at the time of signing informed consent, a regular user (including "recreational

use”) of any illicit drugs or had a recent history (within the last year) of substance abuse (including alcohol) Is pregnant or breastfeeding, or expecting to conceive or father children within the projected duration of the trial •If of childbearing potential, female subjects must be willing to use adequate methods throughout the study, starting with the screening visit through 120 days after the last dose of study therapy • Male subjects with a female partner of child-bearing potential must agree to use adequate methods throughout the trial starting with the screening visit through 120 days after the last dose of pembrolizumab is received. Males with pregnant partners must agree to use a condom; no additional method of contraception is required for the pregnant partner Clinically active diverticulitis, intra-abdominal abscess, GI obstruction or peritoneal carcinomatosis Has a known sensitivity to pembrolizumab or any component of chemotherapy regimen Has pre-existing Grade ≥ 2 peripheral neuropathy Is unable to interrupt aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs), other than an aspirin dose ≤ 1.3 g per day, for a 5-day period

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **295**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be assigned to treatment with the use of stratification, permuted block (length of each block is 3 or 6), and R-CRAN software (version 4.0.3) that will be designed to achieve the overall balance between groups; randomization will be stratified according to Histologic type (squamous vs. non-squamous) and percentage of PDL1 expression (<1, [1-49], ≥50). After randomization procedure, a code will be allocated to each patient that will be used as patient identifier throughout the study. The assigned code will be denoted by 4 initials (corresponding to the first two letters of first name, first two letters of surname) and 3 numbers (center code). Moreover, the code described is followed by the study unique identification code consisting of first three letters of the generic name of the investigational product (which is PEM-) and 3 numbers (corresponding to the randomization number), e.g. ABCD001PEM-001. The randomization number will be assigned in a consecutive way.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both products used in the study will be entirely indistinguishable for patients and health care providers since they are identical in shape, size, Material and color. they don't differ in appearance. The compartments of both pembrolizumab drugs are packaged in same pack. such a way that they do not differ in appearance. The contents of the labels are based on EMEA regulation. The brand's medicine and produced medicine in the factory are completely relabeled and packaged in the same way. The blinding codes are listed on the drug label, and each drug is linked to the patient through the specific code. The patient, medical staff, and other staff are not disclosed to the type of medication that being taken.The group of patients and the type of medication they receive are not disclosed to the researchers and are kept in opaque sealed envelopes with the researcher at each center. In addition, the people who review the results and analyze the data are aware of the type of patient grouping.

Placebo

Not used

Assignment

Parallel

Other design features

The Primary objective of this study is to verify non-inferiority of Pembrolizumab (produced by CinnaGen Co.) compared with Keytruda® in metastatic Non-Small Cell Lung Cancer (NSCLC) patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of National Research Institude of Tuberclulosis and lung Disease Beheshti Universi

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Approval date

2022-03-15, 1400/12/24

Ethics committee reference number

IR.SBMU.NRITLD.REC.1400.117

Health conditions studied

1

Description of health condition studied

Metastatic Non-Small Cell Lung Cancer (NSCLC) patients

ICD-10 code

C34.9

ICD-10 code description

Malignant neoplasm of unspecified part of bronchus or lung

Primary outcomes

1

Description

Progression-Free Survival (PFS) per RECIST 1.1, which is defined as the time from randomization to disease progression or death from any cause.

Timepoint

Every 9 weeks and during the study as needed

Method of measurement

Imaging (CT scan)

Secondary outcomes

1

Description

Overall Survival, which is defined as the time from randomization to death from any cause.

Timepoint

During the study

Method of measurement

Patient medical record

2

Description

Objective response rate (ORR) per RECIST 1.1, which is defined the percentage of people in a study or treatment group who have a partial or complete response to the treatment during the study.

Timepoint

Every 9 weeks

Method of measurement

Imaging (CT scan)

3

Description

Progression-Free Survival (PFS) per iRECIST, which is defined as the time from randomization to disease progression or death from any cause.

Timepoint

Every 9 weeks and during the study as needed.

Method of measurement

Imaging (CT scan)

4

Description

Evaluation of pembrolizumab safety.

Timepoint

Throughout study and during each visit.

Method of measurement

Assessing and recording adverse events and clinically significant laboratory abnormalities.

5

Description

Assessment of anti-drug antibody (ADA) development in patients.

Timepoint

Visits1, 2, 4, 8, 16 and the follow-up visit.

Method of measurement

Blood sampling for the evaluation of anti-drug antibody serum levels.

6

Description

Objective response rate (ORR) per iRECIST, which is defined the percentage of people in a study or treatment group who have a partial or complete response to the treatment during the study.

Timepoint

Every 9 weeks

Method of measurement

Imaging (CT scan)

Intervention groups

1

Description

1) Squamous:- Pembrolizumab (CinnaGen) 200mg IV, every 3 weeks for maximum 51 weeks - Paclitaxel 200 mg/m2 IV, every 3 weeks for maximum 12 weeks (4 cycles)- Carboplatin AUC=6 mg/mL * min IV, every 3 weeks for maximum 12 weeks (4 cycles)2) Non-squamous:- Pembrolizumab (CinnaGen) 200mg IV, every 3 weeks for maximum 51 weeks - Pemetrexed 500mg/m2 IV, every 3 weeks for maximum 51 weeks- Carboplatin AUC=5 mg/mL * min IV, every 3 weeks for maximum 12 weeks (4 cycles), after infusion of pemetrexed.

Category

Treatment - Drugs

2

Description

1) Squamous: - Keytruda® (Merck) 200mg IV, every 3 weeks for maximum 51 weeks- Paclitaxel 200 mg/m2 IV, every 3 weeks for maximum 12 weeks (4 cycles)- Carboplatin AUC=6 mg/mL * min IV, every 3 weeks for maximum 12 weeks (4 cycles)2) Non-squamous:- Keytruda® (Merck) 200mg IV, every 3 weeks for maximum 51 weeks- Pemetrexed 500mg/m2 IV, every 3 weeks for maximum 51 weeks- Carboplatin AUC=5 mg/mL * min IV, every 3 weeks for maximum 12 weeks (4 cycles), after infusion of pemetrexed.

Category

Treatment - Drugs

Recruitment centers

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Sponsors / Funding sources

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
CinnaGen company

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Orchid Pharmed Co.

Full name of responsible person
Dr. Nasim Anjidani

Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available