

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 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-inferiority

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

Registrant information

Name

Nassim Anjidani

Name of organization / entity

Orchid Pharmed

Country

Iran (Islamic Republic of)

Phone

+98 21 4347 3000

Email address

amini@orchidpharmed.com

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 \leq 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 Institute of Tuberculosis and lung Disease Beheshti Universi

Street address

Masih Daneshvari Hospital, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

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

Visits 1, 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

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Dr. Adnan Khosravi, Dr. Sharareh seyfi, Dr. Babak Salimi, Dr.Maryam Mabani

Street address

Shahid Bahonar Ave, Darabad

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 3000

Email

adkhosravi@yahoo.com

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Shahi, Dr. Roudini, Dr. Mirzania, Dr.Amirhossein Emami

Street address

Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1593

Email

Fshahi@yahoo.com

3

Recruitment center

Name of recruitment center

Jahad daneshgahi center

Full name of responsible person

Dr. Safa Najjar Najafi

Street address

No. 45, West nazari St., Aboureyhan St.,Tehran, iran

City

Tehran

Province

Tehran

Postal code

1234567890

Phone

+98 21 6640 4050

Email

safa3n@icbc.ir

4

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Dr. Mohsen Razavi, Dr.Mohammad Mehdi Adib

Street address

Valadi Street, Valiasr Sq., Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1593747811

Phone

+98 21 8893 7902

Email

s_m_raz@yahoo.com

5

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Dr.Sina Salari, Di.Shirin Tahere Haghighi

Street address

Araabi St., Velenjak Region, Chamran High Way, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2293 7031

Email

s.salari@sbm.ac.ir

6

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Dr. Nastaran Khodakarim, Dr.Vahid Kaveh

Street address

Niyayesh St., Satarkhan St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5000

Email

Drfardadf@yahoo.com

7

Recruitment center

Name of recruitment center

Military hospital in Tehran

Full name of responsible person

Dr. Mohsen Rajaei Nejad, Dr.Ali Faridfar

Street address

Etemadzadeh St., West Fatemi St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411718546

Phone

+98 21 8609 6350

Email

mrjajaei@gmail.com

8

Recruitment center

Name of recruitment center

Naft Hospital

Full name of responsible person

Dr. Behrouz Gharib

Street address

Sarhang Sakhaei Street, Hafez Street, , Tehran

City

Tehran

Province

Tehran

Postal code

11367 74114

Phone

+98 21 6670 0023

Email

Gharib.behrooz@yahoo.com

9

Recruitment center

Name of recruitment center

Baqiyatallah Al'Azam Hospital

Full name of responsible person

Dr. Mojtaba Ghadiani, Dr.Reza Agha Bozorgi

Street address

After Sheikh Bahayi, Mollasadra Street, Vanak Square, Tehran

City

Tehran

Province

Tehran

Postal code

14359 15371

Phone

+98 21 81261

Email

ghadianymojtaba@yahoo.com

10

Recruitment center

Name of recruitment center

Shahid Ghazi Hospital

Full name of responsible person

Dr. Ali Esfahani, Dr. Seyed Hadi Chavoshi, Dr.Babak Nejadi

Street address

Golgasht St., Daneshgah St., Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614731

Phone

+98 41 3334 7054

Email

ali_sfhn@yahoo.com

11

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Dr. Alireza Rezvani, Dr. Shirin Haghghat, Dr. Nasrin Namdari, Dr.Abolfazl Khalfi Nejad

Street address

Zand Street, Namaz Square, Shiraz, Fars, Iran

City

Shiraz

Province

Fars

Postal code

1135171937

Phone

+98 61 3647 4332

Email

Dr.rezvani@hotmail.com

12

Recruitment center

Name of recruitment center

Seyedoshohada Hospital

Full name of responsible person

Dr. Mehrzad, Dr. Sharifi, Dr.Nekouee, Dr.Ashrafi, Dr. Derakhshandeh , Dr. Sadeghi

Street address

Amadgah St., Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3235 0219

Email

valimehrzad@yahoo.com

13

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Abolghasem Allahyari, Dr. Mostafa Kamandi

Street address

Imam Reza Sq. Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

allahyari.abolghasem@yahoo.com

14

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Dr. Alireza Bari, Dr. Sajjad Ataei, Dr. Hossein Rahimi,
Dr. Mohammad Moeini

Street address

Ahmad-Abad Street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3840 0000

Email

dr.alireza.baari@gmail.com

15

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Sirous Qarib, Dr. Hossein Mirpoor, Dr. Fatemeh
Nejatifar

Street address

Sardar jangal St, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

4144895655

Phone

+98 13 3354 1001

Email

Dr.cygharib@gmail.com

16

Recruitment center

Name of recruitment center

Shahid Baghaei Hospital

Full name of responsible person

Dr. Mehran Hossein zadeh, Dr. Tina Vosoughi

Street address

Chemotherapy Section, Shahid Baghaei Hospital,
Golestan Road, Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

6138933333

Phone

+98 61 3375 0000

Email

hoseinzadehmehran@gmail.com

17

Recruitment center

Name of recruitment center

Naft Grand Hospital

Full name of responsible person

Dr. Alireza Abu-Ali

Street address

Airport three ways, at the beginning of Naft town
road, Ahvaz, Khuzestan

City

Ahvaz

Province

Khuzestan

Postal code

617351357

Phone

+98 61 3443 6601

Email

Dr.abooali@yahoo.com

18

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital

Full name of responsible person

Dr. Vahid Moazed, Dr. Behjat Kalantari, Dr.Naeim
Nikpoor

Street address

West Qarani St., Kerman

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

dkalantarikhandani@gmail.com

19

Recruitment center

Name of recruitment center

Dr. Mortazavizadeh Clinic

Full name of responsible person

Dr. Mohammad Reza Mortazavi Zade

Street address

No. 25, Shahid Hajmohammadi Alley, First of Shahid Ghandi Blvd, Yazd

City

Yazd

Province

Yazd

Postal code

9874563210

Phone

+98 35 3725 0044

Email

mortazavizadeh@yahoo.com

20

Recruitment center

Name of recruitment center

Shahid Sadooghi Hospital

Full name of responsible person

Dr. Mohammad Foratyazdi

Street address

Ebne Sina St, Shahid Ghandi Blvd, Safaieh

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۸۸۷۸۵۷

Phone

+98 35 3822 4000

Email

foratyazdi@yahoo.com

21

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Rahim Asghari

Street address

Resalat Blvd, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3223 4897

Email

rahimasghari@gmail.com

22

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Ehsan Zaboli, dr. Sina Eslami

Street address

Valiasr highway, Imam Sq., Sari

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3304 4000

Email

Paya_1358@yahoo.com

23

Recruitment center

Name of recruitment center

5th Azar Hospital

Full name of responsible person

Dr. Mohammad Naeimi Tabiee, Dr.Davood Mozafari

Street address

5th Azar Street, Gorgan, Golestan

City

Gorgan

Province

Mazandaran

Postal code

4917761551

Phone

+98 17 3222 0561

Email

drmnaeimi@yahoo.com

24

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital

Full name of responsible person

Dr. Fateme Hamidi, Dr. Mozhan Asadi, Dr. Niloofar Ghodrati

Street address

First of Chalous road, Karaj

City

Karaj

Province

Alborz

Postal code

3154686695

Phone

+98 26 3250 9256

Email

Hamidineda78@yahoo.com

25

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr.Sahar Tavakoli, Dr.Mohammad Vaezi

Street address

Ale-Ahmad Jalal, Karegar St, Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

shariatihosp@tums.ac.ir

26

Recruitment center

Name of recruitment center

Dey Hospital

Full name of responsible person

Dr.Masood Fakharian

Street address

Next to the Abbapoor St, First of Tavanir St, Valiasr St, Tehran

City

Tehran

Province

Tehran

Postal code

1434873111

Phone

+98 21 8879 7111

Email

info@day.generalhospital.ir

27

Recruitment center

Name of recruitment center

Bank Melli Hospital

Full name of responsible person

Dr.Alireza Ahmadi

Street address

Ferdosi Street,Tehran

City

Tehran

Province

Tehran

Postal code

11359311396

Phone

+98 21 6142 0000

Email

info@Bmihis.com

28

Recruitment center

Name of recruitment center

Pardis Noor Niloo

Full name of responsible person

Dr.Mojtaba Gorji

Street address

Next to the Gilan St and Farrokhi Yazdi St, 2nd Boostan, Pasdaran St, Tehran

City

Tehran

Province

Tehran

Postal code

1664855813

Phone

+98 21 9100 8808

Email

Info@pardisnoor.com

29

Recruitment center

Name of recruitment center

Tehran Hospital

Full name of responsible person

Dr.Ali Shahrabi

Street address

Sanaei Sq ,Hosseini St, Karim khan Zand St, Tehran

City

Tehran

Province

Tehran

Postal code

1586746711

Phone

+98 21 8871 2931

Email

info@tehran-hospital.ir

30

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Dr.Mohammad Reza Ozi

Street address

In Front of Health Center, Kamarbandi St, Jomhori Eslami Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Phone

+98 76 3334 7000

Email

info@hums.ac.ir

31

Recruitment center

Name of recruitment center

Parsa mehr Clinic

Full name of responsible person

Dr. Ali HajiGholami

Street address

First Floor NO 2, , Parsian B, 36th Alley, Mirdamad St, Esfahan,Iran

City

Isfahan

Province

Isfahan

Postal code

32367138

Phone

+98 31 3236 7138

Email

alihajigholami@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

CinnaGen company

Full name of responsible person

Dr. Haleh Hamedifar

Street address

Simin Dasht Industrial Park, Karaj, Alborz, Iran

City

Karaj

Province

Alborz

Postal code

3165933155

Phone

+98 26 3667 0980

Email

cinnagen@cinnagen.com

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

Medical Department Manager

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

No 42. Attar sq, Attar st, Valiasr st, Vanak sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1994766411

Phone

+98 21 4347 3000

Email

anjidani.n@orchidpharmed.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Orchid Pharmed Company

Full name of responsible person

Dr. Nasim Anjidani

Position

PharmD./Medical department manager

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

No. 12, 70 Alley, Yousef Abad St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1939653515

Phone

+98 21 4347 3000

Email

Anjidani.n@Orchidpharmed.com

Person responsible for updating data

Contact

Name of organization / entity

Orchid Pharmed Co.

Full name of responsible person

Dr. Nasim Anjidani

Position

Medical Department Manager

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

No 42. Attar sq, Attar st, Valiasr st, Vanak sq, Tehran,
Iran

City

Tehran

Province

Tehran

Postal code

1994766411

Phone

+98 21 4347 3000

Email

anjidani.n@orchidpharmed.com

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