Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Oct 2026

A Phase III, randomized, two armed, parallel, triple-blind, active controlled, equivalency clinical trial to determine the therapeutic efficacy and safety between Pertuzumab® (produced by CinnaGen Co.) plus Trastuzumab, Carboplatin and Docetaxel compared with Perjeta® (Pertuzumab, the reference drug, produced by Roche Company) plus Trastuzumab, Carboplatin and Docetaxel in neoadjuvant treatment of HER 2 positive Breast Cancer patients

Protocol summary

Study aim

efficacy and safety of Pertuzumab® (CinnaGen) compared with Perjeta® (Genentech) in neoadjuvant treatment of HER2+ breast cancer patients

Design

after referral to the researchers, in the case of having informed consent will receive a randomization code, and randomly enter in to one of the two groups of pertuzumab and will receive their regimen and they will be evaluated.

Settings and conduct

All drugs are in the same boxes and vials,there is no apparent difference between the Iranian drug and the brand, and the researchers, patients and the data analyzing team will be completely unaware of the type of the drug.

Participants/Inclusion and exclusion criteria

Inclusion: Female aged 18 -70 ; Operable, locally advanced,inflammatory breast cancer; primary tumor size >2 cm; HER2+; ECOG 0-1, LVEF ≥55% Exclusion: Metastatic (stage IV) or bilateral breast cancer;Previous systemic or local anticancer therapy;other malignancy except for carcinoma in situ of cervix, basal cell carcinoma, or squamous cell carcinoma of skin; Use of another research drug in the four weeks before study;Major surgery four weeks before study; Uncontrolled hypertension; unstable angina, congestive heart failure, serious cardiac arrhythmia needs treatment,myocardial infarction within 6 months of enrollment, Inadequate bone marrow, liver, or renal function; Shortness of breath during rest or any other disease that requires continuous oxygen therapy, any severe uncontrolled systemic disease; Chronic treatment with corticosteroids; HIV,HBV,HCV infections, Hypersensitivity to studied drugs or excipients; Pregnant, lactating; Unwillingness or inability to fulfill the protocol

Intervention groups

A: Pertuzumab(CinnaGen) with Trastuzumab, Docetaxel and Carboplatin B: Perjeta(Genentech) with Trastuzumab, Docetaxel and Carboplatin

Main outcome variables

pathologic complete response

General information

Reason for update

Protocol Amendment

Acronym

IRCT registration information

IRCT registration number: **IRCT20150303021315N11**
Registration date: **2018-06-11, 1397/03/21**
Registration timing: **prospective**

Last update: **2022-02-14, 1400/11/25**
Update count: **4**

Registration date

2018-06-11, 1397/03/21

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

2018-05-22, 1397/03/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

2018-08-05, 1397/05/14

Actual recruitment end date

2019-12-12, 1398/09/21

Trial completion date

2020-05-20, 1399/02/31

Scientific title

A Phase III, randomized, two armed, parallel, triple-blind, active controlled, equivalency clinical trial to determine the therapeutic efficacy and safety between Pertuzumab® (produced by CinnaGen Co.) plus Trastuzumab, Carboplatin and Docetaxel compared with Perjeta® (Pertuzumab, the reference drug, produced by Roche Company) plus Trastuzumab, Carboplatin and Docetaxel in neoadjuvant treatment of HER 2 positive Breast Cancer patients

Public title

Equivalency clinical trial to determine the therapeutic efficacy and safety between Pertuzumab® (produced by CinnaGen Co.) compared with Perjeta® (Pertuzumab, the reference drug, produced by Roche Company)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female patients aged 18 - 70 Operable (T2-3, N0-1, M0), locally advanced (T2-3, N2 or N3, M0; T4a-c, any N, M0), or inflammatory (T4d, any N, M0) breast cancer Primary tumor diameter should be more than 2 centimeters Positive HER2 status approved by immunohistochemistry (IHC 3+ or IHC 2+ verified by fluorescence in situ hybridization (FISH) or chromogenic in situ hybridization (CISH)) Eastern Cooperative Oncology Group performance status (ECOG PS) of 0 or 1 LVEF ≥55% at baseline assessed by echocardiography Able and willing to sign an informed consent

Exclusion criteria:

Metastatic (stage IV) or bilateral breast cancer Previous systemic or local anticancer therapy for any cancer Any other malignancy except for carcinoma in situ of the cervix, basal cell carcinoma, or squamous cell carcinoma of the skin Use of another research drug in the four weeks before the start of the study Major surgery four weeks before the start of the study Uncontrolled hypertension (systolic blood pressure more than 150 mmHg or/and diastolic blood pressure more than 100 mmHg) Inadequate bone marrow, liver, or renal function:ANC < 1500/µLPlt < 100,000/µLHb< 9 g/dLALT/AST > 1.5 ULN (upper limit of normal)ALP > 2.5 ULNTotal serum bilirubin > 1.25 ULNSerum creatinine > 1.5 ULN Shortness of breath during rest or any other disease that requires continuous oxygen therapy Any severe uncontrolled systemic disease (cardiovascular, pulmonary, metabolic, etc.) Chronic treatment with corticosteroids with a daily dose of ≥ 10 mg oral prednisolone or equivalent of other types (other than inhaled corticosteroid drugs) Patients with HIV, HBV, and HCV infections Hypersensitivity to any of the studied drugs or excipients Pregnant, lactating or fertile women who do not want to use contraceptive methods (contraceptives should be taken in to consideration up to six months after the last dose of the drug) Unwillingness or inability to fulfill the requirements of the protocol, including any kind of condition (physical, mental or social) that affects one's ability to fulfill the requirements of the protocol unstable angina congestive heart failure of any class of NYHA (New York Heart Association) serious cardiac arrhythmia needs treatment history of myocardial infarction within 6 months prior to enrollment

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **214**

Actual sample size reached: **214**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be assigned to groups using dynamic randomization, according to these variables: 1- ER/PR: ER/PR+, ER/PR- 2- Type of breast cancer: operable, locally advanced, inflammatory 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 4 numbers (center code). Moreover, the described code is followed by study unique identification code consisting of first two letters of the generic name of the investigational product and study phase number, respectively (PE3), and four numbers (corresponding to the randomization number), e.g. ABCD0001PE3-0001. The randomization number will be assigned in a consecutive way, e.g. 0001, 0002, 0003 and so on until the last.

Blinding (investigator's opinion)

Triple blinded

Blinding description

To prevent the influence of knowing intervention group on study conclusion, the subjects and those who assess the study outcomes will be blinded. For this purpose, subjects and administrator of drug will be blinded by using a similar masked vials.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

opposite 17 Shahrivar Hospital, Shahid siadati St. , Namjou St. , Rasht

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2018-01-27, 1396/11/07

Ethics committee reference number

IR.GUMS.REC1395.444

2

Ethics committee

Name of ethics committee

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Sixth floor, Research Deputy of Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulvard

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

IR.TUMS.VCR.REC.1397.127

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast of unspecified site

Primary outcomes

1

Description

Pathologic Complete Response

Timepoint

before intervention and 3-5 weeks After last intervention

Method of measurement

Pathology laboratory

Secondary outcomes

1

Description

Clinical response rate

Timepoint

before intervention and 3 weeks after last intervention

Method of measurement

Physical examination and imaging (MRI)

2

Description

Rate of breast-conserving surgery

Timepoint

3-5 weeks after last intervention

Method of measurement

Physician report

3

Description

Safety

Timepoint

Every 3 weeks

Method of measurement

Patient’s history and laboratory data

4

Description

Immunogenicity

Timepoint

Every 3 weeks

Method of measurement

Blood test and antidrug antibody presence evaluating

5

Description

total pathological complete response in breast and axillary lymph nodes

Timepoint

3-5 weeks After last intervention

Method of measurement

Pathology laboratory

Intervention groups

1

Description
Intervention group: Study drugs are administered intravenously on a 3-weekly schedule for 6 cycles, and given consecutively on the same day in the following sequence: trastuzumab, followed by pertuzumab (cinnagen), carboplatin, and docetaxel. Trastuzumab is given at an initial dose of 8 mg/kg, followed by 6 mg/kg; pertuzumab is given at an initial dose of 840 mg, followed by 420 mg.

Category
Treatment - Drugs

2

Description
Control group: Control group: Study drugs are administered intravenously on a 3-weekly schedule for 6 cycles, and given consecutively on the same day in the following sequence: trastuzumab, followed by pertuzumab (Perjeta) , carboplatin, and docetaxel. Trastuzumab is given at an initial dose of 8 mg/kg, followed by 6 mg/kg; Perjeta® in group B is given at an initial dose of 840 mg, followed by 420 mg.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehrad Hospital
Full name of responsible person
Dr. Jahangir Raafat
Street address
Mir Emad St.,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1587963110
Phone
+98 21 8874 7401
Email
jahangirraafat@yahoo.com

2

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

3

Recruitment center
Name of recruitment center
Dr Safa Najfi Clinic
Full name of responsible person
Dr. Safa Najjar Najafi
Street address
No. 17, Pardis St.,Molla-sadra St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1234567890
Phone
+98 21 8879 8525
Email
safa3n@icbc.ir

4

Recruitment center
Name of recruitment center
Booali Hospital
Full name of responsible person
Dr. Arash Jenabian - Dr. Abdol-Ali Shahrasbi
Street address
Imam Hossein Square, Beginning Damavand Avenue, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1234567890
Phone
+98 21 3334 8025
Email
arash_jenabian@yahoo.com

5

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Dr Mohsen Esfandbod
Street address
Hassan abad sq. Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1136746911

Phone
+98 21 6634 8500
Email
sfandbod@sina.tums.ac.ir

6

Recruitment center
Name of recruitment center
Emam khomini Hospital
Full name of responsible person
Dr Safaei, Dr. Shahi, Dr. Sadighi, Dr. Esfandbod, Dr. Emami, Dr. Mirzania
Street address
Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14197333141
Phone
+98 21 6658 1593
Email
Fshahi@yahoo.com

7

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Dr. Adnan khosravi
Street address
Darabad, Tehran
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 3000
Email
adkhosravi@yahoo.com

8

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Dr. Hamid Rezvani, Dr.Sina Salari, Dr.Mojtaba Ghadyani, Dr.Hamid attarian
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@sbmu.ac.ir

9

Recruitment center
Name of recruitment center
Firozgar Hospital
Full name of responsible person
Dr. Mohsen Razavi, Dr. Saeed Salimi
Street address
Valiasr Street, Valadi Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8893 7902
Email
s_m_raz@yahoo.com

10

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Dr. Nafiseh Ansari nejhad
Street address
Niyayesh St., Satarkhan St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6651 5000
Email
naffisse@yahoo.com

11

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr Abolqasem Allahyari
Street address
Imam Reza Sq. Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 8543 0311
Email

allahyari.abolghasem@yahoo.com

12

Recruitment center

Name of recruitment center
Dr. Mortazavizadeh Clinic

Full name of responsible person
Dr. Mohammad Reza Mortazavi Zade

Street address
Yazd, Yazd province, Iran,

City
Yazd

Province
Yazd

Postal code
9874563210

Phone
+98 35 3725 0044

Email
mortazavizadeh@yahoo.com

13

Recruitment center

Name of recruitment center
Namazi Hospital

Full name of responsible person
Dr. Mani Ramzi, Dr. Alireza Rezvani, Dr. Mehdi Dehghani

Street address
Zand Street, Namaz Square, Shiraz, Fars, Iran

City
Shiraz

Province
Fars

Postal code
1135171937

Phone
+98 61 3647 4332

Email
Ramzim@sums.ac.ir

14

Recruitment center

Name of recruitment center
Shahid faqihi Hospital

Full name of responsible person
Dr. Shirin Haqiqat joo

Street address
Chamran Blvd, Shiraz, Fars, Iran

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 61 3230 4905

Email
haghighatjoo.sh@gmail.com

15

Recruitment center

Name of recruitment center
Bahonar Hospital

Full name of responsible person
Dr, Bahjat Kalantari, Dr. Vahid Moazed

Street address
Qarani St.,Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7613747181

Phone
+98 34 3223 5011

Email
dkalantarikhandani@gmail.com

16

Recruitment center

Name of recruitment center
Shafa Hospital

Full name of responsible person
Dr. Mehran Hosseinzadeh, Dr Ahmad Ahmadzadeh

Street address
Ahvaz, Khuzestan, Iran

City
Ahvaz

Province
Khouzestan

Postal code
3155

Phone
+98 61 1336 7543

Email
hoseinzadehmehran@gmail.com

17

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Dr. Behrooz Najafi, Dr. Sirous Qarib, Dr. Hossein Mirpoor, Dr. Mehdi Mirbolouk

Street address
Sardar jangal St, Rasht, Iran

City
Rasht

Province
Guilan

Postal code
41448

Phone
+98 13 3354 1001

Email
behrouznajafi@gmail.com

18

Recruitment center

Name of recruitment center
Shams Hospital

Full name of responsible person
Dr Babak Nejati, Dr Ali Esfahani, Dr Alireza Nikanfar, Dr Hadi Chavoshi

Street address
Shams hospital, Between Abresan and Abbasi intersection, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
51665-158

Phone
+98 41 3658 3030

Email
ali_sfhn@yahoo.com

19

Recruitment center

Name of recruitment center
Seyedoshohada Hospital

Full name of responsible person
Dr. Fariborz Mokarian, Dr Valiallah mehrzad, Dr Alireza Sadeghi, Dr Amirabbas Nekouee

Street address
Amadgah St., Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
7346181746

Phone
+98 31 2240 2190

Email
mokarian@med.mui.ac.ir

20

Recruitment center

Name of recruitment center
Sheikh mofid Clinic

Full name of responsible person
Dr. Fariborz Mokarian, Dr.Ali Reza Sadeghi, Dr.Amir Abbas Nekuee, Dr.Valiollah Mehrzad

Street address
Sheikh mofid St., Alzahra clinic, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
1234567980

Phone
+98 31 2368 0050

Email
mokarian@med.mui.ac.ir

21

Recruitment center

Name of recruitment center
Masoud clinic

Full name of responsible person
Dr. Masoud Iravani

Street address
19th street. Amirabad. Tehran Iran

City
Tehran

Province
Tehran

Postal code
0123456789

Phone
+98 21 8874 7401

Email
masoudiravani@gmail.com

22

Recruitment center

Name of recruitment center
Dr Payandeh clinic

Full name of responsible person
Dr. Mehrdad Payandeh

Street address
Shahrdari square- Kermanshah- Iran

City
Kermanshah

Province
Kermanshah

Postal code
0123456789

Phone
+98 83 3728 2400

Email
Drpayandeh@gmail.com

23

Recruitment center

Name of recruitment center
Qaem Hospital

Full name of responsible person
Dr Alireza Bari

Street address
Ahmad-Abad Street, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
99199-91766

Phone
+98 51 3840 0000

Email
dr.alireza.baari@gmail.com

24

Recruitment center

Name of recruitment center
Sanabad Clinic
Full name of responsible person
Dr hossein Rahimi
Street address
Sanabad clinic, Sanabad Street, Mashhad
City
mashhad
Province
Razavi Khorasan
Postal code
0123456789
Phone
+98 51 3843 0606
Email
Info@sanabadclinic.com

25

Recruitment center
Name of recruitment center
Arvand Hospital
Full name of responsible person
Dr Ali Ehsanpour
Street address
Qanaei Street, Shariati Street, Ahwaz
City
Ahwaz
Province
Khouzestan
Postal code
6155635444
Phone
+98 61 3293 3347
Email
drehsanpour@gmail.com

26

Recruitment center
Name of recruitment center
SABA clinic
Full name of responsible person
Dr Mohsen Khani
Street address
Morad-Abad alley, Amadgah Street, isfahan
City
Isfahan
Province
Tehran
Postal code
1234567890
Phone
+98 31 3222 0455
Email
khani.hot@gmail.com

27

Recruitment center
Name of recruitment center
Naft Hospital
Full name of responsible person
Dr Behrouz Gharib
Street address
No. 82, Sakhaei street, Hafez street, tehran
City
Tehran
Province
Tehran
Postal code
0123456789
Phone
+98 21 5417 5000
Email
Gharib.behrooz@yahoo.com

28

Recruitment center
Name of recruitment center
Sajjad Hospital
Full name of responsible person
Dr. Safa Najjar Najafi
Street address
Chemotherapy Section , Sajjad hospital, Chehelston Street, Dr. Fatemi Square, Tehran
City
Tehran
Province
Tehran
Postal code
1431694411
Phone
+98 21 5790 2000
Fax
+98 21 5790 2011
Email
Shahram.Hospital@gmail.com

29

Recruitment center
Name of recruitment center
Tehran Hospital
Full name of responsible person
Dr. Abdol-Ali Shahrasbi
Street address
Chemotherapy Section , Tehran hospital, 7th Tir Square, Karim Khan Zand St, Sanai St, Tehran
City
Tehran
Province
Tehran
Postal code
۱۵۸۵۷۳۷۳۱۱
Phone
+98 21 8882 1021
Fax
+98 21 8831 7298
Email
a.sh@gmail.com

30

Recruitment center

Name of recruitment center
IranMehr Hospital
Full name of responsible person
Dr. Adnan khosravi
Street address
Chemotherapy Section, Iranmohr Hospital, Shariati St, Tehran
City
Tehran
Province
Tehran
Postal code
1949913414
Phone
+98 21 2200 9071
Fax
+98 21 2260 2649
Email
info@iranmehrhospital.ir

31

Recruitment center
Name of recruitment center
Dr Behrooz Najafi Clinic
Full name of responsible person
Dr. Behrooz Najafi
Street address
No. 142 , Dr Behrooz Najafi Clinic , Navab Street , next to Golsar Boarding Pharmacy, Rasht, Gilan
City
Rasht
Province
Guilan
Postal code
1777915311
Phone
+98 13 3211 5049
Email
Bnajafi@gums.ac.ir

32

Recruitment center
Name of recruitment center
Besat Clinic
Full name of responsible person
Dr. Hossein Mirpour - Dr. Sirus Gharib
Street address
Chemotherapy Section, Besat Clinic, Haji Abad Street, Rasht, Guilan
City
Guilan
Province
Guilan
Postal code
1985633753
Phone
+98 13 3326 1448
Email
Dr.cygharib@gmail.com

33

Recruitment center
Name of recruitment center
Dr Mehdi Mirbolouk Clinic
Full name of responsible person
Dr Mehdi Mirbolouk
Street address
Dr Mehdi Mirbolouk Clinic, Medical Doctors Building 8, Galsar Intersection of Asgari Street, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4135663341
Phone
+98 13 3211 3588
Email
mirboloukmahdi@yahoo.com

34

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Dr. Mojtaba Ghadiani
Street address
Chemotherapy Section, Baqiyatallah Hospital, Vanak Square, Tehran
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 81261
Email
ghadianymojtaba@yahoo.com

35

Recruitment center
Name of recruitment center
Resalat Hospital
Full name of responsible person
Dr. Amir Hossein Emami
Street address
Chemotherapy Section, Resalat Hospital, Abouzar Ghaffari Street, Resalat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1661613781
Phone
+98 21 2286 9647
Email
emamiami@sina.tums.ac.ir

36

Recruitment center

Name of recruitment center
Toos Hospital

Full name of responsible person
Dr. Mohsen Razavi

Street address
Chemotherapy Section, Toos Hospital, Motahhari St., Valiasr Square, Tehran

City
Tehran

Province
Tehran

Postal code
۱۵۹۶۹۳۳۱۱۱

Phone
+98 21 8871 4891

Email
s_m_raz@yahoo.com

37

Recruitment center

Name of recruitment center
Dr. Allahyari Clinic

Full name of responsible person
Dr Abolqasem Allahyari

Street address
No.6, Next to Asian Insurance, Chamran Ave, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
0123456789

Phone
+98 51 3858 3050

Email
allahyari.abolghasem@yahoo.com

38

Recruitment center

Name of recruitment center
Dr, Bahjat Kalantari Clinic

Full name of responsible person
Dr, Bahjat Kalantari

Street address
Dr, Bahjat Kalantari Clinic, Park Building, Neshat Park , Kerman

City
Kerman

Province
Kerman

Postal code
32265003

Phone
+98 34 3226 5003

Email
dkalantarikhandani@gmail.com

39

Recruitment center

Name of recruitment center
Jawad Al-Ameh Hospital

Full name of responsible person
Dr. Vahid Moazed

Street address
Chemistry Section., Jawad al-Ameh Hospital, Alley No. 25, Abu Dharmalm Ave., Kerman

City
kerman

Province
Kerman

Postal code
32510025

Phone
+98 34 3251 0025

Email
Moazed_vahid@yahoo.com

40

Recruitment center

Name of recruitment center
Shahid Baghaei Hospital

Full name of responsible person
Dr. Mehran Hosseinzadeh

Street address
Chemotherapy Section, Shahid Baghaei Hospital, Golestan Road, Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
33750000

Phone
+98 61 3375 0000

Email
hoseinzadehmehran@gmail.com

41

Recruitment center

Name of recruitment center
Milad Hospital

Full name of responsible person
Dr. Fariborz Makarian - Dr. Valiollah Mehrzad

Street address
Chemotherapy Section, Milad Hospital, Shahid Bakhshi Street, Janbazan Blvd, Isfahan

City
Esfahan

Province
Isfehan

Postal code
37774009

Phone
+98 31 3777 4009

Email
valimehrzad@yahoo.com

42

Recruitment center
Name of recruitment center
Ebn-Sina Hospital
Full name of responsible person
Dr Behrouz Gharib
Street address
Chemotherapy Section , Ebn-Sina Hospital, Ayatollah Kashani Boulevard, Tehran
City
Tehran
Province
Tehran
Postal code
47909000
Phone
+98 21 4790 9000
Email
gharib.behrooz@yahoo.com

43

Recruitment center
Name of recruitment center
Amir Hospital
Full name of responsible person
Dr. Alireza Rezavani
Street address
Chemotherapy section, Amire shiraz Hospital, Farhang Shahr, Shiraz
City
Shiraz
Province
Fars
Postal code
7187915998
Phone
+98 71 3632 3731
Email
Dr.rezvani@hotmail.com

44

Recruitment center
Name of recruitment center
Jam Hospital
Full name of responsible person
Dr Arash Jenabian
Street address
chemotherapy section, jam Hospital, Fajr Street, Shahid Motahri Street, Tehran
City
Tehran
Province
Tehran
Postal code
1588657915
Phone
+98 21 8882 0091
Email
arash_jenabian@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
CinnaGen company
Full name of responsible person
Somayeh Amini
Street address
No 2, Khorasani deadend, Derakhti St, Dadman St, Shahrak-eGharb
City
Tehran
Province
Tehran
Postal code
1425614985
Phone
+98 21 4347 3000
Email
Amini.s@orchidpharmed.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 Company
Full name of responsible person
Dr. Nasim Anjidani
Position
Pharmacist, Clinical Trial Manager
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
No 10, Ninth street, Iranzamin Blvd, Shahrak-e-Gharb
City
Tehran
Province
Tehran
Postal code
1465884171

Phone
+98 21 8808 8821
Fax
Email
anjidani.N@orchidpharmed.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Orchid Pharmed Company
Full name of responsible person
Somayeh Amini
Position
PharmD./Medical department manager
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
no 2, Emad khorassani D.D, Derakhti St, Dadman Blvd, shahrake Gharb
City
Tehran
Province
Tehran
Postal code
1468813112
Phone
+98 21 4347 3210
Fax
Email
amini.s@orchidpharmed.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Orchid Pharmed Company
Full name of responsible person
Dr. Nasim Anjidani
Position
Pharmacist, Clinical Trial Manager
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
No.2, khorasani Alley, Derakhti Ave, dadman blvd, Shahrak-e-Gharb
City
Tehran
Province
Tehran
Postal code
1465884171
Phone
+98 21 8808 8821
Fax
Email
Anjidani.N@orchidpharmed.com
Web page address

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