

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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 Anjidan

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 $\geq$ 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/ μ LPlt < 100,000/ μ LHb< 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 $\geq$ 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 Boulevard

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 nejhadi
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

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

Khuzestan

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. Siros 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 Valiollah mehrzad, Dr
Alireza Sadeghi, Dr Amirabbas Nekouee

Street address

Amadgah St., Isfahan, Iran

City

Isfahan

Province

Isfahan

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 Nekouee, Dr.Valiollah Mehrzad

Street address

Sheikh mofid St., Alzahra clinic, Isfahan, Iran

City

Isfahan

Province

Isfahan

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

Isfahan

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