

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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**

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2018-06-11, 1397/03/21

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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 ≥ 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

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Ethics committee reference number

IR.GUMS.REC1395.444

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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

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1

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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 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

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Latest degree
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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