Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of efficacy and safety of PADYNEX (Trastuzumab-emtansine, T-DM1, manufactured by Nano Daru Pajuhan Pardis) in women with human epidermal growth factor receptor 2 (HER2) positive metastatic breast cancer: A randomised controlled trial, two-arm, open-label.

Protocol summary

Study aim

Comparison of efficacy and safety of Padynex and trastuzumab in women with HER2 positive metastatic breast cancer

Design

A randomised controlled trial, Phase II, two-arm, open-label with a group of 150 patients. In this study, women with human epidermal growth factor receptor 2 (HER2) positive metastatic breast cancer will receive a 1:2 ratio of padynex and trastuzumab, respectively. Randomization is based on the method of random permuted blocks.

Settings and conduct

Shohadaye Tajrish hospital, Firoozgar hospital; This study is an open label clinical trial; In first group, patients will receive Padynex at a dose of 3.6 mg per kilogram of body weight every 3 weeks for 6 cycles, the second group will be assigned to the treatment of trastuzumab.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18-75 years HER2+ Metastatic breast cancer (Metastasis to intraperitoneal solid organs, lungs, pleura, or multiple bones) Exclusion criteria: History of type 1 allergic/anaphylactic infusion reactions to any component of the PADYNEX formulation. History of treatment with trastuzumab-emtansine. Patients with locally advanced breast cancer and non metastatic. Patients with brain metastasis.

Intervention groups

Intervention group 1 includes patients with HER2+ metastatic breast cancer who will receive Padynex. Intervention group 2 includes patients with HER2+ metastatic breast cancer who will receive trastuzumab.

Main outcome variables

Objective response rate; gastrointestinal disorders such as vomiting, constipation and diarrhea; pain; blood disorders such as Neutropenia, anemia, leukopenia and thrombocytopenia; Alanine aminotransferase levels, aspartate aminotransferase levels; fever; peripheral neuropathy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201223049810N1**
Registration date: **2021-02-02, 1399/11/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-02, 1399/11/14**
Update count: **0**

Registration date

2021-02-02, 1399/11/14

Registrant information

Name

Hanieh yadollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of efficacy and safety of PADYNEX (Trastuzumab-emtansine, T-DM1, manufactured by Nano Daru Pajuhan Pardis) in women with human epidermal growth factor receptor 2 (HER2) positive metastatic breast cancer: A randomised controlled trial, two-arm, open-label.

Public title
Evaluation of efficacy and safety of PADYNEX in women with HER2+ metastatic breast cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 18-75 years Metastatic breast cancer (Metastasis to intraperitoneal solid organs, lungs, pleura, or multiple bones) Based on histological, cytological and imaging results. HER2+ (immunohistochemistry 3+, HER2 gene amplification in fluorescence in situ hybridization positive or positive HER2 result in Chromogenic in situ hybridization). Patients with measurable disease based on Response Evaluation Criteria in Solid Tumors, version 1.1, (the minimum size of a measurable lesion at baseline should be no less than double the slice thickness (when CT scans have slice thickness greater than 5 mm, the minimum size for a measurable lesion should be twice the slice thickness)). Life expectancy of more than 12 weeks based on a physician or treatment team estimate. Acceptable clinical test results at the beginning of the study based on the normal range of the reporting laboratory An Eastern Cooperative Oncology Group performance status of 0–2 All the patients provided written informed consent.
Exclusion criteria:
History of type 1 allergic/anaphylactic infusion reactions to any component of the PADYNEX formulation History of treatment with trastuzumab-emtansine Patients with locally advanced breast cancer and non metastatic History of second non-breast cancer in last 5 year Patients with brain metastasis Serious concurrent disease (chronic kidney disease stage 4,5, hepatic impairment child pugh class c, bronchiectasis, severe chronic obstructive pulmonary disease, severe asthma, pulmonary fibrosis) Peripheral neuropathy of grade 3 or worse (as per National Cancer Institute Common Terminology Criteria for Adverse Events [NCI CTCAE] version 5.0) Left ventricular ejection fraction lower than 50% (as measured by echocardiography) within previous 3 months, myocardial infarction or congestive heart failure within previous 6 months, high-risk uncontrolled arrhythmias; clinically significant valvular disease; concomitant medication for the treatment of unstable angina, uncontrolled blood pressure (higher than 200/100 mmHg), severe electrical conduction defect (having a pacemaker or electrocardiogram diagnosis) or Any other significant heart disease. Blood disorders such as baseline absolute neutrophil count lower or equal to 1,500 per microliter or platelet count lower or equal to 100,000 per microliter. Alanine aminotransferase/ aspartate aminotransferase higher or equal to 2.5 upper limit of normal. Pregnancy, breast-feeding, and women of childbearing potential not using contraception.
Age
From **18 years** old to **75 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is based on the method of random permuted blocks. In this study, the following four blocks will be used: AABB, ABAB, ABBA, BBAA, BABA, BAAB First, one of these six blocks is randomly selected and individuals are assigned to two groups based on it (for example, if the first selected block is ABAB, the first patient is group A, the second patient is group B, the third patient is group A, and the fourth patient is assigned to group B. Then the next four blocks are selected and this process will continue until the sample is completed. Randomization will be performed using SAS statistical software version 9.4.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Third Floor, Faculty of Medicine, Next to Taleghani Hospital, Evin, Shahid Chamran Highway, Tehran
City
Tehran
Province
Tehran
Postal code

1985717434

Approval date

2020-12-03, 1399/09/13

Ethics committee reference number

IR.SBMU.CRC.REC.1399.030

Health conditions studied

1

Description of health condition studied

Human epidermal growth factor receptor 2 (HER2) positive metastatic breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Objective Response Rate

Timepoint

before starting treatment, 77 and 105 day after starting treatment

Method of measurement

computerized tomography scan or Magnetic resonance imaging, According to Response Evaluation Criteria in Solid Tumors (RECIST; version 1.1)

Secondary outcomes

1

Description

pain score

Timepoint

Pain score will be assessed at 21, 42, 63, 84, 105 and 126 days after starting the treatment.

Method of measurement

The grade (severity) of pain will be assessed by visual analog scale.

2

Description

Vomiting

Timepoint

The grade of Vomiting will be assessed at 21, 42, 63, 84, 105 and 126 days after starting treatment.

Method of measurement

Case report form

3

Description

Diarrhea

Timepoint

The grade of diarrhea will be assessed at 21, 42, 63, 84, 105 and 126 days after starting treatment.

Method of measurement

Case report form

4

Description

Constipation

Timepoint

The grade of constipation will be assessed at 21, 42, 63, 84, 105 and 126 days after starting treatment.

Method of measurement

Case report form

5

Description

Neutropenia

Timepoint

The grade of neutropenia will be assessed at 21, 42, 63, 84, 105 and 126 days after starting treatment.

Method of measurement

Taking a blood test from the patient; Nihon Kodhen ES Hematology Analyzer based on flow cytometry method

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Description

Anemia

Timepoint

The grade of anemia will be assessed at 21, 42, 63, 84, 105 and 126 days after starting treatment.

Method of measurement

Taking a blood test from the patient; Nihon Kodhen ES Hematology Analyzer based on flow cytometry method.

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Description

Leukopenia

Timepoint

The grade of leukopenia will be assessed at 21, 42, 63, 84, 105 and 126 days after starting treatment.

Method of measurement

Taking a blood test from the patient; Nihon Kodhen ES Hematology Analyzer based on flow cytometry method

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Description

Thrombocytopenia

Timepoint

The grade of thrombocytopenia will be assessed at 21, 42, 63, 84, 105 and 126 days after starting treatment.

Method of measurement

Taking a blood test from the patient; Nihon Kodhen ES Hematology Analyzer based on flow cytometry method

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Description

Alanine aminotransferase levels

Timepoint

The grade of alanine aminotransferase will be assessed

at 21, 42, 63, 84, 105 and 126 days after starting treatment.

Method of measurement

BT3500 analyzer based on enzymatic method

10

Description

Aspartate aminotransferase levels

Timepoint

The grade of aspartate aminotransferase, will be assessed at 21, 42, 63, 84, 105 and 126 days after starting treatment.

Method of measurement

BT3500 analyzer based on enzymatic method

11

Description

Fever

Timepoint

The grade of fever will be assessed at 21, 42, 63, 84, 105 and 126 days after starting treatment.

Method of measurement

Thermometer

12

Description

Peripheral neuropathy

Timepoint

The grade of peripheral neuropathy will be assessed at 21, 42, 63, 84, 105 and 126 days after starting treatment.

Method of measurement

Case report form

Intervention groups

1

Description

Intervention group: 50 women with human epidermal growth factor receptor 2 (HER2) positive metastatic breast cancer, receiving Padynex (trastuzumab-emtansine, T-DM1 manufactured by Nano Daru Pajuhan Pardis) at a dose of 3.6 mg per kg by intravenous infusion every three weeks for 6 cycles.

Category

Treatment - Drugs

2

Description

Control group: 100 women with human epidermal growth factor receptor 2 (HER2) positive metastatic breast cancer, receiving trastuzumab; Loading dose of 8 mg per kg body weight of patients, and 3 weeks after loading dose, maintenance dose of 6 mg per kg body weight by intravenous infusion, every three weeks for 6 cycles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Mohsen Razavi

Street address

Firoozgar hospital, Behafarin St., Karimkhan Zand St., Valiasr Sq., Tehran, Iran.

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2

Recruitment center

Name of recruitment center

Shohadaye Tajrish hospital

Full name of responsible person

Hamidreza Mirzaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nano Daru Pajuhan Pardis Company

Full name of responsible person

Hanieh Yadollahi

Street address

NO. 4, Northern Tak Ave., Attar St., Vanak Sq., Tehran, Iran.

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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

Nano Daru Pajuhan Pardis 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

Nano Daru Pajuhan Pardis Company

Full name of responsible person

Hanieh Yadollahi

Position

Pharmacist

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

pharmacist

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Hanieh Yadollahi

Position

Pharmacist

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

In the participants data file, only part of the data will be shared as the main outcome.

When the data will become available and for how long

1 year after publication of result

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

At the request of researchers working in academic and scientific institutions

From where data/document is obtainable

Hanieh Yadollahi Email: h.yadollahi@nanodaru.com

What processes are involved for a request to access data/document

Up to 3 months after request

Comments