

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Aug 2026

Comparison of Paclinab serum level with its original serum brand, Abraxane in patients with metastatic breast cancer

Protocol summary

Study aim

Bioequivalence evaluation of Paclitaxel protein-bound particles in Iranian patients with breast cancer

Design

A randomized, two-treatment, two-period, cross over study

Settings and conduct

Strength: 260 mg/m² dose administered in 30 minutes
Subjects: 18 metastatic Breast cancer patients The place of study is Firoozgar hospital. Five mL of venous blood is obtained before the start of the infusion, at 15 min after the start of the infusion, 2 to 5 min before the end of the infusion, and at 0.5, 1, 1.5, 2, 4, 6, 8, 12, 24, and 48 h after the end of the infusion. This is a single-blind and cross over study. The washout period is 3 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria -Breast cancer patients after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy
hemoglobin $\geq$ 9 g/dl, ANC $\geq$ 1,500/mm³, platelet count $\geq$ 100,000/mm³, serum creatinine $\leq$ 2 mg/dl, and serum bilirubin $\leq$ 1.5 mg/dl, Hepatic transaminases should be less than threefold of the upper limit of normal. - Patients should be nonpregnant and non-lactating
Exclusion criteria -Use of drugs or supplements known to influence the expression and function of CYP3A4 and/or CYP2C8 are excluded from the study - Patients who experience a severe hypersensitivity reaction to ABRAXANE should not be rechallenged with the drug

Intervention groups

First intervention: Single dose administration of Paclinab® (paclitaxel protein-bound particles for injectable suspension) manufactured by Nano Daru pharma Co. in patients with metastatic breast cancer
Second intervention: Single dose administration of Abraxane® (paclitaxel protein-bound particles for injectable suspension) manufactured by Abraxis BioScience Co. in patients with metastatic breast cancer

Main outcome variables

drug concentration in blood plasma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130603013572N6**

Registration date: **2021-02-01, 1399/11/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-01, 1399/11/13**

Update count: **0**

Registration date

2021-02-01, 1399/11/13

Registrant information

Name

Mohammadreza Rouini

Name of organization / entity

Tehran University of Medical Sciences, Faculty of Pharmacy

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Paclitaxel serum level with its original serum brand, Abraxane in patients with metastatic breast cancer

Public title
Comparison of paclitaxel albumin-bound nanoparticles serum level with its original serum brand, Abraxane, in patients with metastatic breast cancer

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
 - Breast cancer patients after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy hemoglobin ≥ 9 g/dl
 Female patients should be nonpregnant and non-lactating ANC $\geq 1,500/\text{mm}^3$ platelet count $\geq 100,000/\text{mm}^3$ serum creatinine < 2 mg/dl serum bilirubin < 1.5 mg/dl Hepatic transaminases should be less than threefold of the upper limit of normal.
Exclusion criteria:
 -Use of drugs or supplements known to influence the expression and function of CYP3A4 and/or CYP2C8 -
 Patients who experience a severe hypersensitivity reaction to ABRAXANE should not be rechallenged with the drug

Age
From **18 years** old

Gender
Female

Phase
Bioequivalence

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **18**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization Adminstrating of test or reference product for each subject is determined according to the randomization schedule. The randomization schedule is prepared according to entrancing of subject to the study. Each subject is identified by a number from 1 to 18 according to entrancing of subject to the study to volunteers' list in screening day. Subjects with odd numbers receive the test drug and the subjects with even number receive the reference drug and vice versa. (test or reference is the same drug but produced with different manufacturers).

Blinding (investigator's opinion)
Single blinded

Blinding description
The study is a single-blind. Subjects are blind in this

study. Patients are aware of what medication they are taking but do not know whether they are taking the test or reference drug in the first or second period (in one group, the test drug is prescribed in the first period and the reference drug in the second period and in the second group the reference drug is prescribed in the first period and the test drug in the second period). The main investigator creates a table using randomization and divides 18 patients in 2 groups which only he knows the details of group. Test or reference drug is injectable powder and prepared base on its brochure, so patients are blinded regarding to the kind of drugs. Subjects are aware that they are receiving the test drug (Iranian) and the reference drug (approved drug), but they do not know in which study period they will receive the test and reference drug. Test or reference is the same drug but produced with different manufacturers, so there is not any intervention in treatment.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Vice Chancellor for International affairs, Iran
University of Medical Sciences, Shahid Hemmat
Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2020-06-01, 1399/03/12

Ethics committee reference number

IR.IUMS.REC.1399.279

Health conditions studied

1

Description of health condition studied

bioequivalence, pharmacokinetics

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

determination of drug concentration in blood plasma

Timepoint

0 min (pre-dose), 15 , 30 min (during infusion), 0.5, 1, 1.5, 2, 4, 6, 8, 12, 24, 48 h after the end of infusion

Method of measurement

High performance liquid chromatography

Secondary outcomes

1

Description

time to peak plasma concentration

Timepoint

0 min (pre-dose), 15 , 30 min (during infusion), 0.5, 1, 1.5, 2, 4, 6, 8, 12, 24, 48 h after the end of infusion

Method of measurement

observational

2

Description

Area under the plasma concentration-time curves

Timepoint

0 min (pre-dose), 15 , 30 min (during infusion), 0.5, 1, 1.5, 2, 4, 6, 8, 12, 24, 48 h after the end of infusion

Method of measurement

linear trapezoidal method

3

Description

maximum plasma concentration

Timepoint

0 min (pre-dose), 15 , 30 min (during infusion), 0.5, 1, 1.5, 2, 4, 6, 8, 12, 24, 48 h after the end of infusion

Method of measurement

observational

Intervention groups

1

Description

Intervention group: Single dose administration of Paclinab® (paclitaxel protein-bound particles for injectable suspension) (260 mg/m² as an IV infusion over 30 minutes) manufactured by Nano Daru pharma Co. in patients with metastatic breast cancer

Category

Other

2

Description

Control group: Single dose administration of Abraxane® (paclitaxel protein-bound particles for injectable suspension) manufactured by Abraxis BioScience Co. in patients with metastatic breast cancer

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar medical education

Full name of responsible person

Dr. Vahid Kaveh

Street address

Firoozgar Center, Beh Afarin St., Karim Khan St., Valiasr Square, Tehran

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kaveh_vahid@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nano Daru pharmaceutical Co.

Full name of responsible person

Dr. Navid Godarzi

Street address

Northern Tak Ave., Attar St., Vanak Sq., Tehran, Iran

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Tehran

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Tehran

Postal code

1994754953

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Email

godarzi@nanodaru.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nano Daru pharmaceutical Co.

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Rouini

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics and Biopharmaceutics

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

No - There is not 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

Only protocol and methods of study are shareable

When the data will become available and for how long

Starting access 6 months after publication of data

To whom data/document is available

Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used

Using is not authorized

From where data/document is obtainable

contact with E-mail of the main researcher

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

Personal and academic details and the aim of data request.

Comments