Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Oct 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 ≥ 9 g/dl, ANC ≥ 1,500/mm3, platelet count ≥ 100,000/mm3, serum creatinine ˂ 2 mg/dl, and serum bilirubin ˂ 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-bouñd 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

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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 Paclinab 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$_9$ 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 ≥ 1,500/mm3 platelet count ≥ 100,000/mm3 serum creatinine ˂ 2 mg/dl serum bilirubin ˂ 1.5 mg/d 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 Administrating 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

۱۴۴۹۶۱۴۵۳۵

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
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Firoozgar Center, Beh Afarin St., Karim Khan St., Valiasr Square, Tehran
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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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Province
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Postal code
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Phone
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Email
goodarzi@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
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Ph.D.
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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