Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Randomized, single-dose, crossover comparative bioequivalence study of the Macitentan 10 mg tablets produced by Nano Fanavaran Darouyi Alvand pharmaceutical Co versus Opsumit® (Janssen company) in 24 healthy males under fasting conditions

Protocol summary

Study aim

To demonstrate bioequivalence of single dose test formulation of Nano Fanavaran Darouyi Alvand Macitentan 10 mg tablets versus Opsumit®(Janssen Co.)

Design

Single dose, randomized and crossover bioequivalence study of Macitentan 10 mg tablets by Nano Fanavaran Darouyi Alvand with Opsumit® (Janssen Co.) in 24 healthy male

Settings and conduct

Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. Place for Blood and plasma sample analysis: Imam Reza Medical Research and Trainning Hospital. 24 healthy male volunteers will receive each of two test or reference Macitentan 10 mg tablets in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days. Blood samples of volunteers at 0 (before dosing), 1، 2، 4، 5، 5.5، 6، 6.5، 7، 7.5، 8، 8.5، 9، 9.5، 10 ،12، 24، 36 ، 48 and 72 hour after dosing will be collected.

Participants/Inclusion and exclusion criteria

Healthy male subjects in the age range of 18-60 years with BMI (Body Mass Index) of 18.5-30. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Candidates who have consented to the informed consent form. Exclusion criteria: Known hypersensitivity or idiosyncratic reaction to Macitentan or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily.

Intervention groups

Intervention group 1: Macitentan 10 mg tablet produced by Nano Fanavaran Darouyi Alvand Co. is the test product. Intervention group 2: Macitentan 10 mg tablets (Opsumit), produced by Janssen Company is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product.

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N18**
Registration date: **2021-10-09, 1400/07/17**
Registration timing: **prospective**

Last update: **2021-10-09, 1400/07/17**
Update count: **0**

Registration date

2021-10-09, 1400/07/17

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized, single-dose, crossover comparative bioequivalence study of the Macitentan 10 mg tablets produced by Nano Fanavaran Darouyi Alvand pharmaceutical Co versus Opsumit® (Janssen company) in 24 healthy males under fasting conditions

Public title

Study of absorption and elimination rate of Macitentan 10 mg tablets in comparison with standard tablets of Macitentan (Opsumit®).

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy male subjects in the age range of 18-60 years with BMI (Body Mass Index) of 18.5-30. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Candidates who have consented to the informed consent form.

Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to Macitentan or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily.

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of the both groups will change for the second period.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Science

Street address

Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-08-02, 1400/05/11

Ethics committee reference number

IR.TBZMED.REC.1400.472

Health conditions studied

1

Description of health condition studied

In this study, the disease is not examined. The subject of the study is the bioequivalence study of the Macitentan 10 mg of test and reference in healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

At 0 (before dosing), 1، 2، 4، 5، 5.5، 6، 6.5، 7، 7.5، 8، 8.5، 9، 9.5، 10 ،12، 24، 36 ، 48 and 72 hour after dosing

Method of measurement

High-performance liquid chromatography—mass spectrometry (HPLC-MS)

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint
At 0 (before dosing), 1، 2، 4، 5، 5.5، 6، 6.5، 7، 7.5، 8، 8.5، 9، 9.5، 10 ،12، 24، 36 ، 48 and 72 hour after dosing
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description
Intervention group 1: Macitentan 10 mg tablet produced by Nano Fanavaran Darouyi Alvand Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group 2: Macitentan 10 mg tablets (Opsumit), produced by Janssen Company is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center
Full name of responsible person
Dr Hamed Hamishehkar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nano Fanavaran Darouyi Alvand pharmaceutical Co
Full name of responsible person
Nima Sepehri
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No. 1462, Center of pharmaceutical incubator, Next to University Alley, Above Jalal Al-Ahmad, North Amirabad St., Tehran University of Medical Sciences,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 Fanavaran Darouyi Alvand 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
Tabriz University of Medical Sciences
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Hamed Hamishehkar
Position
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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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available