Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative bioequivalence study of the Domperidone suspension 1 mg/ml (200 mL) produced by Omid Behboud pharmaceutical Co versus Motilium® (Janssen company)

Protocol summary

Study aim

Demonstration of bioequivalence of Domperidone suspension 1 mg/mL of Omid Behboud Pharmaceutical Company with Motilium® suspension manufactured by Janssen after single dose administration.

Design

Single dose, randomized and crossover bioequivalence study of Domperidone suspension 1 mg/mL by Omid Behboud Co. with Motilium ® (Janssen) in 24 healthy male volunteers in two groups.

Settings and conduct

Study place and the place for blood sample analysis are the Drug Applied Research Center affiliated to Tabriz University of Medical Science, respectively. 24 healthy male volunteers will receive 20 cc of the two 1mg/ml domperidone suspensions test or reference in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before and after receiving the drug at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6 , 8, 12, 24, 36 and 48 hours after dosing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18-30. Exclusion criteria: Subjects with Blood Pressure ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of tuberculosis, epilepsy, asthma, diabetes, psychosis or glaucoma and regular smoker.

Intervention groups

Intervention group 1: Domperidone suspension 1 mg/mL by Omid Behboud Co. is the test product. Intervention group 2: Motilium ® (Janssen) is the reference product. In each period, 12 of 24 subjects will be given single dose of this product. After the washout period, the volunteers are placed in the opposite group.

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: **IRCT20200407046981N31**
Registration date: **2022-05-19, 1401/02/29**
Registration timing: **prospective**

Last update: **2022-05-19, 1401/02/29**
Update count: **0**

Registration date

2022-05-19, 1401/02/29

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 2700

Email address

molavif@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-21, 1401/03/31

Expected recruitment end date

2022-10-22, 1401/07/30

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

Scientific title
Comparative bioequivalence study of the Domperidone suspension 1 mg/ml (200 mL) produced by Omid Behboud pharmaceutical Co versus Motilium® (Janssen company)

Public title
Study of absorption and elimination rate of Domperidone suspension 1 mg/ml in comparison with Domperidone brand suspension (Motilium®).
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The weight limit of each volunteer should be between 60 and 100 kg. All volunteers must be non-smokers. 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 consent form.
Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Domperidone 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. Taking any medicine during two weeks before dosing.
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
2021-12-12, 1400/09/21
Ethics committee reference number
IR.TBZMED.REC.1400.938

Health conditions studied

1

Description of health condition studied
Bioequivalence study
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)
Timepoint
At 0 (before dosing), 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 12, 24, 36 and 48 hour after dosing
Method of measurement
High-performance liquid chromatography—mass spectrometry (HPLC-MS-MS)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
At 0 (before dosing), 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 12, 24, 36 and 48 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: In this group, volunteers are given a single oral dose of Domperidone suspension 1 mg/mL produced by Omid Behboud Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 2.

Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of Domperidone suspension 1 mg/mL (Motilium®), produced by Janssen Company (Brand). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 1.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Drug Applied Research Center

Full name of responsible person
Hamed Hamishehkar

Street address
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Phone
+98 41 3336 7914

Fax
+98 41 3336 7914

Email
Hamishehkar.hamed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Omid Behboud Pharmaceutical Co.

Full name of responsible person
Nilufar Kazemi Ali Akbar

Street address
Third Floor, No. 37, Qaem Maqam-e-Farahani Ave, Haft-Tir Sq, Tehran

City
Tehran

Province
Tehran

Postal code
1589943835

Phone
+98 21 8832 1861

Fax
+98 21 8832 1861

Email
joudaki@omidbehboud.com

Grant name

Grant code / Reference number

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

Title of funding source
Omid Behboud 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

Full name of responsible person
Hamed Hamishehkar

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutics

Street address
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Phone
+98 41 3336 7914

Email
Hamishehkar.hamed@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Jaber Emami

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutics

Street address
Hezarjarib St., School of Pharmacy and Pharmaceutical Sciences , Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 7111

Fax
+98 31 3668 0011

Email
Emami@pharm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Fatima Molavi

Position
Non-Faculty Academic Position

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutics

Street address
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Phone
+98 41 3336 7914

Email
F.molavi85@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

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
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
No - There is not a plan to make this available