

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A randomized, open label, two treatments, single dose, crossover, bioequivalence study of Domperidone 10mg tablet of Amin Pharm Co., IRAN in comparison of Motilium 10mg tablet of Janssen in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

A randomized, crossover bioequivalence study of single dose of test formulation (Domperidone 10mg tablet of Amin Pharm Co., IRAN) in comparison of reference product (Motilium 10mg tablet of Janssen) by means of AUC_{0-t} and C_{max} in healthy adult human subjects under fasting conditions.

Design

A randomized, open label, single dose, crossover, bioequivalence study in 24 healthy subjects under fasting condition

Settings and conduct

This study is carried out in Core Research Center of Zahedan University of Medical Sciences located in Imam Ali Hospital in Zahedan. There is a separate space for sampling and forecasting emergency situations in order to accommodate and rest the volunteers. This crossover and open label study was performed on 24 healthy volunteers. The volunteers' health is verified by the project physician prior to entry into the study, and the volunteers' status is regularly monitored by the project physician on the day of drug administration. This study will be covered by insurance in order to compensate for any adverse effects.

Participants/Inclusion and exclusion criteria

Main Inclusion criteria: Healthy subjects aged between 18 -50 years old and weighted between 50 - 100 kg\\
Main exclusion criteria: Clinically relevant deviations from normal; Donation a unit of blood or participated in another clinical trial within the last two months; History of drug or alcohol abuse; Used any medication within 7-14 days before the first treatment;

Intervention groups

Intervention: Single dose of two Domperidone 10mg tablets of Amin Pharm Co, IRAN Control: Single dose of two Motilium 10mg tablets of Janssen

Main outcome variables

Plasma concentration of Domperidone at 0 (before dosing), 0.25, 0.5, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0, 6.0, 8.0, 10.0, 24 & 48hr. after dosing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N24**
Registration date: **2021-12-31, 1400/10/10**
Registration timing: **prospective**

Last update: **2021-12-31, 1400/10/10**

Update count: **0**

Registration date

2021-12-31, 1400/10/10

Registrant information

Name

Ladan Tayebi

Name of organization / entity

Pars Biopharmacy Research Co.

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 6061

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized, open label, two treatments, single dose, crossover, bioequivalence study of Domperidone 10mg tablet of Amin Pharm Co., IRAN in comparison of Motilium 10mg tablet of Janssen in 24 healthy adult subjects under fasting condition

Public title

Bioequivalence study of Domperidone 10mg tablet of Amin Pharm Co., IRAN

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

- Aged between 18 - 50 years - Body weight between 50 - 100 kg - Having good health on the basis of medical history and physical & clinical examination - Understand the procedures and give written informed consent

Exclusion criteria:

Subject had undergone surgery of the gastro-intestinal tract Subject had donated a unit of blood or participated in another clinical trial, within the last two months before the first treatment. Subject had a history of drug or alcohol abuse. Subject who smokes more than 10 cigarettes per day. Subject had used any prescription medication within 14 days, or any non-prescription medication within 7 days, before the first treatment.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **48**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each volunteer, 2 times take medicine in the study. One-time test product and the other time reference product with at least one week wash-out period.

Randomization (investigator's opinion)

Randomized

Randomization description

Using the rand command in Excel software, one of the sequences AB (test-reference product) or BA (reference-test product) is randomly assigned to each volunteer at random.

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 Zahedan University of medical Sciences

Street address

Dr. Hessabi square Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2021-12-12, 1400/09/21

Ethics committee reference number

IR.ZAUMS.REC.1400.310

Health conditions studied**1****Description of health condition studied**

Anti emetic

ICD-10 code

T45.0X1A

ICD-10 code description

Poisoning by antiallerg/antiemetic, accidental, init

Primary outcomes**1****Description**

Plasma concentration of Domperidone

Timepoint

at 0 (before dosing), 0.25, 0.5, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0, 6.0, 8.0, 10.0, 24 & 48hr. after dosing

Method of measurement

Using High Performance Liquid Chromatography (HPLC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Domperidone, two 10mg tablets, produced by Amin Pharm Co. (IRAN), single dose

Category

Other

2

Description

Control group: Motilium, two 10mg tablets, produced by Janssen , single dose

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Core Research Lab. of ZAUMS

Full name of responsible person

Marzyeh Ghasemi

Street address

Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway

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<http://crl.zaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Amin Pharm. Co.

Full name of responsible person

Mohammad Mahdy Hoghoughi

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Nejatbakhsh Boulevard

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Province

Isfahan

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Email

info@aminpharma.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Amin Pharm. 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

Pars Biopharmacy Research Co.

Full name of responsible person

Ladan Tayebi

Position

Managing Director

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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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

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

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