

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence study of domperidone suspension 1 mg/ml of Sina pishgam Darou Novin pharmaceutical company compared to domperidone 1 mg/ml sample of JANSSEN CILAG company of Belgium on healthy volunteers

Protocol summary

Study aim

Bioequivalence study of domperidone suspension 1 mg/ml of Sina pishgam Darou Novin pharmaceutical company compared to domperidone 1 mg/ml sample of JANSSEN CILAG company in Belgium on healthy volunteers

Design

The current clinical trial includes the study of bioequivalence of Domperidone 1 mg/ml suspension product of Sina pishgam Darou Novin Pharmaceutical Company compared to Domperidone 1 mg/ml sample of JANSSEN CILAG Company, Belgium, after administration to 24 healthy human volunteers, in two intervention groups, in a cross-over manner. , is not blinded and non-randomized.

Settings and conduct

The study is carried out at Nik Azma Pars Alborz Company, located in Mahdasht Karaj, Imam Khomeini Blvd., Azadegan Square, No. 419. The blinded cross-over study includes two stages (oral consumption of 20 ml of domperidone suspension 1 mg/ml in each study and 2 times in total) with a one-week washout period on 24 fasting healthy volunteers. Blood samples are taken from volunteers at certain intervals of drug consumption, and then the amount of domperidone in plasma is determined by liquid chromatography-fluorescence.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy volunteers between the ages of 18 and 50 should be non-smokers. Exclusion criteria: volunteers with blood pressure less than 90 over 60 mm Hg or higher than 140 over 90 mm Hg.

Intervention groups

The study includes two stages as intervention 1: including oral consumption of domperidone suspension 1 mg/ml manufactured by Sina pishgam Darou Novin pharmaceutical company in Iran and intervention 2: oral

consumption of domperidone suspension 1 mg/ml manufactured by JANSSEN CILAG company in Belgium. This study will be repeated on fasting volunteers in a cross-sectional manner with an interval of one week.

Main outcome variables

Maximum plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057495N7**

Registration date: **2023-07-03, 1402/04/12**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-03, 1402/04/12**

Update count: **0**

Registration date

2023-07-03, 1402/04/12

Registrant information

Name

Monireh Jalalipour

Name of organization / entity

Nikazma Pars Alborz company

Country

Iran (Islamic Republic of)

Phone

+98 26 3731 8748

Email address

info@naplab.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2024-06-30, 1403/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of domperidone suspension 1 mg/ml of Sina pishgam Darou Novin pharmaceutical company compared to domperidone 1 mg/ml sample of JANSSEN CILAG company of Belgium on healthy volunteers

Public title

Bioequivalence study of domperidone suspension 1 mg/ml

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy volunteers aged between 18 and 50 years All candidates must be non-smokers Body mass index less than 30 kg per square meter

Exclusion criteria:

Blood pressure less than 90 over 60 mm Hg or more than 140 over 90 mm Hg Consumption of any drugs, alcohol or tobacco products within 2 weeks before receiving the drug

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: **24**

More than 1 sample in each individual

Number of samples in each individual: **28**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Research Institute of Pharmaceutical Sciences,
Tehran University of Medical Sciences

Street address

Institute of Pharmaceutical Sciences, Faculty of
Pharmacy, Tehran University of Medical Sciences,
Porsina Street

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2023-07-01, 1402/04/10

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.049

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

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Maximum plasma concentration of domperidone

Timepoint

Before taking the drug and: 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5,
3, 4, 6, 8, 10 and 24 hours after taking the drug

Method of measurement

Liquid Chromatography - Fluorescence

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: includes oral administration of Domperidone suspension 1 mg/ml manufactured by Sina pishgam Darou Novin Pharmaceutical Company of Iran on 24 healthy fasting volunteers. 5 ml of blood at time intervals before starting the drug and: 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10 and 24 It is taken from the volunteers one hour after taking the medicine. The cross-over study consists of two phases (oral administration of 20 ml of domperidone suspension 1 mg/ml per study and

2 times in total) with a one-week washout period (when the drug is completely removed from your blood). . Domperidone plasma concentration is determined by liquid chromatography-fluorescence method. The analysis of the results will be based on ANOVA and t-test statistical methods.

Category

Other

2**Description**

Intervention group 2: includes the oral use of domperidone suspension 1 mg/ml made by JANSSEN CILAG company in Belgium on 24 fasting healthy volunteers. 5 ml of blood at time intervals before starting the drug and: 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10 and 24 It is taken from the volunteers one hour after taking the medicine. The cross-over study consists of two phases (oral administration of 20 ml of domperidone suspension 1 mg/ml per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). . Domperidone plasma concentration is determined by liquid chromatography-fluorescence method. The analysis of the results will be based on ANOVA and t-test statistical methods.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Nik Azma Pars Alborz Laboratory

Full name of responsible person

Monireh Jalalipour

Street address

No. 419, Azadegan Square, Imam Khomeini Boulevard

City

Mahdasht Karaj

Province

Alborz

Postal code

3188913179

Phone

+98 26 3731 8748

Email

info@naplab.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sina Pishgam Darou Novin Pharmaceutical Company

Full name of responsible person

Zeynab Khansefid

Street address

Sina Building, No. 28, Fourth Alley, North Kargar St.

City

Tehran

Province

Tehran

Postal code

1413694163

Phone

+98 21 8863 0176

Email

info@sinapishgamdarou.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sina Pishgam Darou Novin Pharmaceutical Company

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**

Nik Azma Pars Alborz laboratory

Full name of responsible person

Monireh Jalalipour

Position

Responsible Pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No. 419, Azadegan Square, Imam Khomeini Boulevard

City

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Phone

+98 26 3731 8748

Email

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Nik Azma Pars Alborz laboratory

Full name of responsible person

Monireh Jalalipour

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Nik Azma Pars Alborz laboratory

Full name of responsible person

Monireh Jalalipour

Position

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آدرس خیابان No. 419, Azadegan Square, Imam

Khomeini Boulevard

City

Mahdasht Karaj

Province

Alborz

Postal code

3188913179

Phone

+98 26 3731 8748

Email

info@naplab.ir

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