

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of Domperidone 10 mg F.C. Tablet of ACTOVERCO and Janssen Inc. in 24 healthy male under fasting

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Domperidone 10 mg F.C. Tablet formulation as a test product with Motilium® tablet formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Domperidone 10 mg F.C. Tablet of Actover. and Janssen. in 24 healthy male under fasting.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Farabi Clinic (Eslamshahr, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria

Healthy subjects should be between 18 - 45 years of age and their Body Mass Index (BMI) should be in the normal range according to the accepted average values between 18.5 and 30 (inclusive), calculated as kg/m². Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination, and laboratory evaluations.

Intervention groups

Intervention group (test): Domperidone 10 mg F.C. Tablet, produced by Actover is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group (Reference): Motilium® capsule, produced by Janssen is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N12**

Registration date: **2021-10-22, 1400/07/30**

Registration timing: **retrospective**

Last update: **2021-10-22, 1400/07/30**

Update count: **0**

Registration date

2021-10-22, 1400/07/30

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

Phone

+98 21 6600 7026

Email address

info@tavaninstitute.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-12, 1399/03/23

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Domperidone 10 mg F.C. Tablet of ACTOVERCO and Janssen Inc. in 24

healthy male under fasting	Not blinded
Public title	Blinding description
Bioequivalence study of Domperidone 10 mg F.C. Tablet in 24 healthy male under fasting conditions	Placebo
Purpose	Not used
Treatment	Assignment
Inclusion/Exclusion criteria	Crossover
Inclusion criteria:	Other design features
Healthy subjects should be between 18 – 45 years of age and their Body Mass Index (BMI) should be in the normal range according to the accepted average values between 18.5 and 30 (inclusive), calculated as kg/m ² . Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination, and laboratory evaluations. Have a ECG and normal vital signs. Subjects who agree with the patient consent form.	Secondary Ids
Exclusion criteria:	empty
History of allergy or idiosyncrasy to domperidone or any of the inactive components of the formulation. If you have or have a history of arrhythmia, including tachycardia or ventricular fibrillation, increased QT interval, bradycardia, or heart failure. Identify electrolyte disturbances and water loss due to diarrhea, vomiting or other causes 24 hours before the study. Bleeding or obstruction of the gastrointestinal tract during the last 6 weeks. In case of acute or chronic diseases related to the cardiovascular, respiratory, gastrointestinal, endocrine, blood and kidney or liver failure systems. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who have used any drug including prescription or Over-The-Counter (OTC) drugs within 14 days prior to the start of the study and might need drug intake during the study period. History of alcohol or drug abuse within 5 years before the start of the study. Heavy drinker of caffeine, grapefruit juice, or caffeinated drinks or who are on a special diet (such as vegetarians) or do exertional physical activity. A history of difficulty with donating blood or donation of more than 450 ml blood within 60 days prior to the start of the study.	Ethics committees
Age	1
From 18 years old to 45 years old	Ethics committee
Gender	Name of ethics committee
Male	Ethics committee of Shahid Beheshti University of Medical Sciences
Phase	Street address
Bioequivalence	Niayesh Highway, Valiasr Ave, Tehran, Iran
Groups that have been masked	City
No information	Tehran
Sample size	Province
Target sample size: 26	Tehran
Randomization (investigator's opinion)	Postal code
Randomized	1996835113
Randomization description	Approval date
The randomization schedule will be generated with the BEAR statistical software (Release V2.7.7). Each volunteer will be randomly assigned to one of the 2 different sequence of treatments according to the order of entering the study which will be allocated after screening.	2020-02-03, 1398/11/14
Blinding (investigator's opinion)	Ethics committee reference number
	IR.SBMU.PHARMACY.REC.1398.268
	Health conditions studied
	1
	Description of health condition studied
	Bioequivalence investigation of the generic Actover.Domperidone 10 mg F.C. Tablet with brand Motilium® Janssen capsule.
	ICD-10 code
	ICD-10 code description
	Primary outcomes
	1
	Description
	Peak Plasma Concentration (C _{max})
	Timepoint
	During 2 months after intervention
	Method of measurement
	using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)
	Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint

During 2 months after intervention

Method of measurement

using non-compartmental model of Win-Nonlin
Professional software version 3.2.A (Pharsight
Corporation, USA)

Intervention groups

1

Description

Intervention group: Intervention group: (test):
Domperidone 10 mg F.C. Tablet, produced by Actover 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: Intervention group: Domperidone 10
mg F.C. Tablet, produced by Janssen is the test 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

Hakim Farabi Clinic

Full name of responsible person

Ebrahim Siahpoosh

Street address

No. 57, Shemshad alley, Sallor city

City

Tehran

Province

Tehran

Postal code

4635314588

Phone

+98 21 9253 5647

Email

mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ACtover Pharmaceutical Co.

Full name of responsible person

Nahaleh Naraghi

Street address

58 plaque, 8th St., Gisha

City

Tehran

Province

Tehran

Postal code

1446863914

Phone

+98 21 4162 7000

Email

info@actoverco.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

ACtover 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

Noor Research & Development Institute

Full name of responsible person

Ali Aghaei

Position

Master

Latest degree

Master

Other areas of specialty/work

pharmacy

Street address

Sharif innovation station, North Habibollah, Hosseini
Squ., Teymouri St., Tarasht

City

Tehran

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Tehran

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1459926609

Phone

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Email

info@tavaninstitute.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tavan Institute

Full name of responsible person

Seyed Mohsen Foroutan

Position

Principal investigator

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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City

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Latest degree

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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

It's not specified yet.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not 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

Person responsible for updating data

Contact

Name of organization / entity

Tavan Institute

Full name of responsible person

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Position

Master