Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A randomized, open label, single dose, crossover, bioequivalence study of Mebeverin 135mg tablet of Actover Co., IRAN in comparison of Duspatalin 135mg tablet of Abbott in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim
A randomized, open label, single dose, crossover, bioequivalence study of Mebeverin 135mg tablet of Actover Co., IRAN in comparison of Duspatalin 135mg tablet of Abbott in 24 healthy adult subjects under fasting condition

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 to 50 years old and weighted between 50 to 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: Mebeverin 135mg tablet, produced by Actover Co., (IRAN), single dose. Control: Duspatalin 135mg tablet, produced by Abbott Company, single dose.

Main outcome variables
Plasma concentration of DMAC (demethylmebeverine acid) and Mebeverine acid at 0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0 & 24.0 hr. after dosing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190706044111N38**
Registration date: **2024-10-20, 1403/07/29**
Registration timing: **prospective**

Last update: **2024-10-20, 1403/07/29**
Update count: **0**

Registration date
2024-10-20, 1403/07/29

Registrant information

Name
Ladan Tayebi

Name of organization / entity
Pars Biopharmacy Research Co.

Country
Iran (Islamic Republic of)

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+98 21 8895 6061

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2025-10-23, 1404/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized, open label, single dose, crossover, bioequivalence study of Mebeverin 135mg tablet of Actover Co., IRAN in comparison of Duspatalin 135mg tablet of Abbott in 24 healthy adult subjects under fasting condition

Public title

Bioequivalence study of Mebeverin 135mg tablet of Actover Co., IRAN

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 18 to 50 years Body weight between 50 to 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: **24**

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 Excel software, each subject will be randomly assigned to one of the two sequence AB or BA in a balanced manner.

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

2024-09-15, 1403/06/25

Ethics committee reference number

IR.ZAUMS.REC.1403.245

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Plasma concentration of DMAC (demethylmebeverine acid) and Mebeverine acid

Timepoint

at 0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0 & 24.0 hr. after dosing

Method of measurement

Using High Performance Liquid Chromatography wit Mass Spectrometer detector (HPLC/MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mebeverin 135mg tablet, produced by Actover Co., (IRAN), single dose.
Category
Other

2

Description
Control group: Duspatalin 135mg tablet, produced by Abbott Company, single dose.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Core Research Lab. of ZAUMS
Full name of responsible person
Majid Sartipi
Street address
Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actover Pharm. Co.
Full name of responsible person
Reza Karimi Mostofi
Street address
No 58, 8th St, Kouye Nasr St
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1446863914
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Fax
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Email
ladantayebi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Actover 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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Position

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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