Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A randomized, open label, single dose, crossover, bioequivalence study of Mebeverin 200mg capsule of Actover Co., IRAN and Clofac 200mg capsule of Solvey in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

A randomized, open label, single dose, crossover, bioequivalence study of Mebeverin 200mg capsule of Actover Co., IRAN and Clofac 200mg capsule of Solvey 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 -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 three months; History of drug or alcohol abuse; Used any medication within 7-14 days before the first treatment;

Intervention groups

Intervention: Mebeverin 200mg capsule, produced by Actover Co., (IRAN), single dose. Control: Clofac 200mg capsule, produced by Solvey 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: **IRCT20190706044111N29**
Registration date: **2022-11-12, 1401/08/21**
Registration timing: **prospective**

Last update: **2022-11-12, 1401/08/21**
Update count: **0**

Registration date

2022-11-12, 1401/08/21

Registrant information

Name
Ladan Tayebi
Name of organization / entity
Pars Biopharmacy Research Co.
Country
Iran (Islamic Republic of)
Phone
+98 21 8895 6061
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-11-22, 1402/09/01

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 200mg capsule of Actover Co., IRAN and Clofac 200mg capsule of Solvey in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Mebeverin 200mg capsule of Actover 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: **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
Names or codes assigned to volunteers are entered in a column of the Excel program. In the other column, using the rand command, a number between 0 and 1 is randomly assigned to each volunteer. Then, based on the order of the numbers (for example, from the smallest number to the largest), the first 12 people are placed in the AB sequence (test-reference) and the next 12 people are in the BA sequence (reference-test).
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
2022-07-24, 1401/05/02
Ethics committee reference number
IR.ZAUMS.REC.1401.142

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 MS detector (HPLC/MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mebeverin 200mg capsule, produced by Actover Co., (IRAN), single dose
Category
Other

2

Description
Control group: Clofac 200mg capsule, produced by Solvey company, single dose.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Core Research Lab. of ZAUMS
Full name of responsible person
Ebrahim Kord
Street address
Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway
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Province
Sistan-va-Balouchestan
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9816743111
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+98 54 3329 5665
Email
crl@zaums.ac.ir
Web page address
http://crl.zaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actover Pharm. Co.
Full name of responsible person
Nahaleh Naraghi
Street address
No 58, 8th St, Kouye Nasr St
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Province
Tehran
Postal code
1446863914
Phone
+98 21 4163 7000
Fax
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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 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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Person responsible for scientific inquiries

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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