Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative bioequivalence study of the Mebeverin HCl extended-release Tablet 135 mg, manufactured by Daana Pharma Company vs Colofac® tablets manufactured by Abbott Company in healthy volunteers

Protocol summary

Study aim

Examining the bioequivalency of domestically produced Mebeverin HCl extended-release tablet formulations with brand one named Colofac®

Design

A cross over, not blinded, randomized, bioequivalence clinical trial on 24 healthy volunteers.

Settings and conduct

Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. The number of 24 volunteers in the age range of 18-50 years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification. One tablet is taken fasting and blood is taken at 15 time points. a week later, the process is repeated for the brand medicine

Participants/Inclusion and exclusion criteria

Inclusion criteria: the weight range of 60-100 kg; being non-smoker; being healthy in terms of physical examination, ECG and the laboratory tests; Volunteers who have agreed to an informed consent form. Exclusion criteria: History of allergic or adverse reaction to Mebeverin HCl or any similar product; blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg; Individuals who have donated whole blood during the previous 2 months of the study or donated blood components within 2 weeks before taking the first dose of the drug

Intervention groups

Intervention group 1:Mebeverin HCl 135 mg tablets by Daana Pharma Company is the test product. Intervention group 2: Colofac® by Abbott company is the reference product. In each period, 12 of 24 subjects will be given single dose of this product and for up to 24 hours, 3 ml of blood will be collected from the volunteer at 15 time points each time. After the washout period, the volunteers are placed in the opposite group.

Main outcome variables

Plasma concentration of the drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130313012810N46**
Registration date: **2025-01-02, 1403/10/13**
Registration timing: **prospective**

Last update: **2025-01-02, 1403/10/13**
Update count: **0**

Registration date

2025-01-02, 1403/10/13

Registrant information

Name

Hamed Hamishehkar

Name of organization / entity

Drug Applied Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 3311

Email address

hamishehkar.hamed@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-09, 1403/10/20

Expected recruitment end date

2025-01-11, 1403/10/22

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of the Mebeverin HCl extended-release Tablet 135 mg, manufactured by Daana Pharma Company vs Colofac® tablets manufactured by Abbott Company in healthy volunteers

Public title
Mebeverine HCl tablet bioequivalence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers All candidates must be non-smokersCandidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose. Volunteers who have agreed to an informed consent form. All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw
Exclusion criteria:
History of allergic or adverse reaction to Mebeverine HCl or any similar product. Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg. Individuals who have donated whole blood during the last 2 months from the study Individuals who have donated donated blood components within 2 weeks before taking the first dose of 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**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive Intervention 1 and Group B will receive Intervention 2, and after the first period, the interventions of both groups will change for the second period.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Drug Applied Research Center, Tabriz University of Medical Sciences, Daneshgah Street,Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5165665811
Approval date
2024-11-11, 1403/08/21
Ethics committee reference number
IR.TBZMED.REC.1403.640

Health conditions studied

1

Description of health condition studied
Bioequivalence study in healthy volunteers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of the drug
Timepoint
15 sampling time included pre-dose (time 0) and at the following hours post-dose: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12 and 24 hr
Method of measurement
Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: which consists of 24 healthy and fasting volunteers, will receive a Mebeverin HCl extended-release 135 mg tablet manufactured by Daana Pharma Company.
Category
Treatment - Drugs

2

Description
Intervention group 2: which consists of 24 healthy and fasting volunteers, will receive a Colofac® tablet with a dose of 135 mg manufactured by Abbott Company.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Hamed Hamishehkar
Street address
Drug Applied Research Center, Tabriz University of Medical Sciences, Daneshgah Street,Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
51656-65811
Phone
+98 41 3336 3311
Email
hamishehkar.hamed@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Daana pharmaceutical company
Full name of responsible person
Ahmad Kharazi
Street address
Daana pharmaceutical company, Zanjan-Tabriz Road, Basmanj
City
Tabriz
Province
East Azarbaijan
Postal code
5495151673
Phone
+98 41 3630 0586
Email
name@domain.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Daana 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
Tabriz University of Medical Sciences
Full name of responsible person
Hamed Hamishehkar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Drug Applied Research Center, Tabriz University of Medical Sciences, Daneshgah Street,Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
51656-65811
Phone
+98 41 1336 3311
Fax
+98 41 1336 3311
Email
hamishehkar.hamed@gmail.com
Web page address
http://darc.tbzmed.ac.ir/

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Hamed Hamishehkar

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Drug Applied Research Center, Tabriz University of Medical Sciences, Daneshgah Street,Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
51656-65811

Phone
+98 41 3336 3181

Fax
+98 41 3336 3311

Email
hamishehkar.hamed@gmail.com

Web page address
http://darc.tbzmed.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Hamed Hamishehkar

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Drug Applied Research Center, Tabriz University of Medical Sciences, Daneshgah Street,Tabriz

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Fax
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hamishehkar.hamed@gmail.com

Web page address
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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
No - There is not 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