Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Comparative bioequivalence study of the Lithium carbonate 300-mg tablets manufactured by Ahran Tejarat Pharmaceutical Company versus standard tablets (Sun Pharma)

Protocol summary

Study aim

Demonstration of bioequivalence of Lithium carbonate 300-mg tablet of Ahran Tejarat Pharmaceutical Company with SunPharma tablet after single dose administration

Design

Single dose, randomized and crossover bioequivalence study of lithium carbonate 300-mg tablet by Ahran Tejarat Co. with lithium carbonate (Sun Pharma) in 24 healthy male volunteers in two groups under fasting condition.

Settings and conduct

Study place and the place for Blood sample analysis are the Drug Applied Research Center affiliated to Tabriz University of Medical Science, respectively. 24 healthy male volunteers will receive each of test or reference Lithium carbonate 300-mg tablet in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 14 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before and after receiving the drug at 0 (before dosing), 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 12, 24, 48, 72 and 96 hours after dosing

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-50 years and BMI (Body Mass Index) of 18-30. Exclusion criteria: Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of TB, epilepsy, asthma, DM, psychosis or glaucoma and regular smoker.

Intervention groups

Intervention group 1: Lithium carbonate 300-mg tablet by Ahran Tejarat Co. is the test product. Intervention group 2: Lithium carbonate by Sun Pharma is the reference product. In each period, 12 of 24 subjects will be given single dose of this product. After the washout period, the volunteers are placed in the opposite group

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N32**
Registration date: **2022-05-23, 1401/03/02**
Registration timing: **prospective**

Last update: **2022-05-23, 1401/03/02**
Update count: **0**

Registration date

2022-05-23, 1401/03/02

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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molavif@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-22, 1401/04/31

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of the Lithium carbonate 300-mg tablets manufactured by Ahran Tejarat Pharmaceutical Company versus standard tablets (Sun Pharma)

Public title

Study of absorption and elimination rate of Lithium carbonate 300-mg tablets in comparison with Lithium carbonate standard tablets manufactured by Sun Pharma.

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

The weight limit of each volunteer should be between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Candidates who have consented to the consent form.

Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to Lithium carbonate or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two weeks before dosing.

Age

From **18 years** old to **50 years** old

Gender

Male

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**

In each period, 12 of 24 subjects will be given single dose of this product (Domestic or brand). After the washout period, the volunteers are placed in the opposite group

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 the both groups will change for the second period.

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 Tabriz University of Medical Science

Street address

Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.TBZMED.REC.1401.128

Health conditions studied

1

Description of health condition studied

Bioequivalence study

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

At 0 before dosing, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 12, 24, 48, 72 and 96 hours

Method of measurement

Inductively coupled plasma spectroscopy (ICP)

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint
At 0 before dosing, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 12, 24, 48, 72 and 96 hours
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of Lithium carbonate 300-mg tablet produced by Ahran Tejarat Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 2.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group 2: In this group, volunteers are given a single oral dose of Lithium carbonate-300 tablet , produced by Sun Pharma Company (Brand). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 1.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center
Full name of responsible person
Hamed Hamishehkar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahran Tejarat Pharmaceutical Company
Full name of responsible person
Farinaz Hakimion
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No.27, Sharifi St. North Gandi Ave. Tehran, Iran.
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Email
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https://ahranco.com/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahran Tejarat 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
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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
There is no further information
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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available