

# 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  $\leq$  90/60 mm/Hg or BP  $\geq$  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)

##### Phone

+98 41 3336 2700

##### Email address

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 science

**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  $\leq$  90/60 mm/Hg or BP  $\geq$  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

##### Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

##### City

tabriz

##### Province

East Azarbaijan

##### Postal code

5165665811

##### Phone

+98 41 3336 7914

##### Fax

+98 41 3336 7914

##### Email

hamishehkar.hamed@gmail.com

##### Web page address

<https://darc.tbzmed.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahran Tejarat Pharmaceutical Company

##### Full name of responsible person

Farinaz Hakimion

##### Street address

No.27, Sharifi St. North Gandhi Ave. Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1969813638

##### Phone

+98 21 8865 0472

##### Fax

+98 21 8878 0628

##### Email

info@ahran.com

##### Web page address

<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

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Pharmaceutics

##### Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

##### City

tabriz

**Province**

East Azarbaijan

**Postal code**

5165665811

**Phone**

+98 41 3336 7914

**Fax****Email**

Hamishehkar.hamed@gmail.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Jaber Emami

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pharmaceutics

**Street address**

Hezarjarib St., School of Pharmacy and Pharmaceutical Sciences , Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 7111

**Fax**

+98 31 3668 0011

**Email**

Emami@pharm.mui.ac.ir

**Web page address**

## Person responsible for updating data

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Fatima Molavi

**Position**

Non-Faculty Academic Position

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pharmaceutics

**Street address**

ایران، تبریز، خیابان دانشگاه، روبروی بیمارستان شهید مدنی،  
مجمع تحقیق و توسعه دانشگاه علوم پزشکی تبریز، مرکز  
تحقیقات کاربردی دارویی

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665811

**Phone**

+98 41 3336 7914

**Email**

F.molavi85@gmail.com

## 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