

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Bioequivalence study of Tetrabenazine Tablet 25 mg manufactured by Hoogar Daru company

#### Protocol summary

##### Study aim

Bioequivalence study of Tetrabenazine Tablet 50 mg manufactured by Hoogar Daru Company

##### Design

Clinical trials of single blind design of 48 volunteers

##### Settings and conduct

After selecting the volunteers, Tetrabenazine drug manufactured by Hoogar Daru Company from Iran and by Lundbeck Inc of America will be prescribed to them orally in two doses with an interval of 7 days. For example, if in the first period of the drug administration, the volunteer received the drug manufactured by Hoogar Daru, in the next turn, the volunteer will receive the drug manufactured by Lundbeck Inc. Each time the amount of 6 cc of blood will be taken before drug administration and at times of 0.33, 0.67, 1, 1.25, 1.5, 1.75, 2, 2.5, 3, 4, 6, 9, 12, 24 hour after the medication is prescribed. The next sampling will 7 days later. In the second time, similar to the first time of drug administration, blood sampling will be done. In the next step, the serum and plasma of each sample are separated by centrifuge and the amount of drug in each sample is determined by liquid extraction method and using Lc Mass Mass. The study will be done in Hezareh Sevom Futuristic Pharmacist company

##### Participants/Inclusion and exclusion criteria

Healthy volunteers with no chronic or acute use of any drug at least 1 week before starting the study

##### Intervention groups

Volunteers will be divided into two groups: On the first week, group one will receive Tetrabenazine of Hoogar Daru company and group number two will receive Tetrabenazine of Lundbeck Inc. On the second week, group number one will receive Tetrabenazine of Lundbeck Inc and group number two will receive Tetrabenazine of Hoogar Daru company (cross over)

##### Main outcome variables

Maximum plasma concentration; area under the curve; the time taken to reach maximum plasma concentration

#### General information

##### Reason for update

##### Acronym

(Bioequivalence Tetrabenazine Tablet ) BRT

##### IRCT registration information

IRCT registration number: **IRCT20200625047913N4**

Registration date: **2021-02-02, 1399/11/14**

Registration timing: **prospective**

Last update: **2021-02-02, 1399/11/14**

Update count: **0**

##### Registration date

2021-02-02, 1399/11/14

##### Registrant information

##### Name

Tayebeh Ghari

##### Name of organization / entity

Hezareh Sevom Futuristic Pharmacist Company

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8865 2343

##### Email address

info@hezareh-co.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-21, 1400/02/31

##### Expected recruitment end date

2021-06-21, 1400/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Bioequivalence study of Tetrabenazine Tablet 25 mg manufactured by Hoogar Daru company

**Public title**

Bioequivalence study of Tetrabenazine Tablet 25 mg manufactured by Hoogar Daru company

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

18 to 45 years old Sex: Males and/or non-pregnant, non-lactating females BMI: 18.5 to 24.9 weight in kg/(height in meter) Able to communicate effectively with study personnel and willingness to follow the protocol requirements as evidenced by written informed consent A physical examination with no clinically significant finding and laboratory normal tests Do not take any chronic or acute medication for at least 1 week before the start of the study No history of diseases affecting the pharmacokinetic processes of the drug

**Exclusion criteria:**

History of allergic responses to Tetrabenazine or other related drugs, or any of its formulation ingredients Have significant diseases (which might compromise the haemopoietic, gastrointestinal, renal, hepatic, cardiovascular, respiratory, central nervous system, diabetes, psychosis or any other body system) or clinically significant abnormal findings during screening Smokers who smoke 10 or more cigarettes per day or 20 or more biddies per day or those who cannot refrain from smoking during the study period History or evidence of drug dependence or of alcoholism or of moderate alcohol use. Volunteers who have received a known investigational drug within five elimination half life of the administered drug prior to the initial dose of study drug or who have participated in a clinical drug study or bioequivalence study within 90 days prior to the initial dose of study drug, whichever is greater found positive in urine test for drugs of abuse done before check-in of period History of difficulty in swallowing, or of any gastrointestinal disease which could affect drug absorption

**Age**

From **18 years** old to **45 years** old

**Gender**

Both

**Phase**

Bioequivalence

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Tetrabenazine drug manufactured by Hoogar Daru Company from Iran and by Lundbeck Inc of America will

be prescribed to them orally in two doses with an interval of 7 days. For example, if in the first period of the drug administration, the volunteer received the drug manufactured by Hoogar Darura, in the next turn, the volunteer will receive the drug manufactured by Lundbeck Inc. No one knows which medication will be administrated in each week.

**Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

First floor, Building number 1 of school of medicine, North Door of the University, Poursina St, Ghods St, Enghelab St, Tehran. Iran

**City**

تهران

**Province**

Tehran

**Postal code**

1417653911

**Approval date**

2021-01-26, 1399/11/07

**Ethics committee reference number**

IR.TUMS.TIPS.REC.1399.158

**Health conditions studied****1****Description of health condition studied**

-

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Plasma concentration

**Timepoint**

0.33, 0.67, 1, 1.25, 1.5, 1.75, 2, 2.5, 3, 4, 6, 9, 12, 24 hour

**Method of measurement**

LC Mass Mass

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Prescription of Tetrabenazine 25 mg tablets made by Hoogar Daru company from Iran in the first week

### Category

Other

2

### Description

Control group: Prescription of Tetrabenazine 25 mg tablets made by Lundbeck Inc from America in the Second week

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Hezareh Sevom Futuristic Pharmacist Company

#### Full name of responsible person

Tayebeh Ghari

#### Street address

Unit 4, No. 81, Babak Bahrami st, After Zafar st, Tehran, Iran.

#### City

Tehran

#### Province

Tehran

#### Postal code

1968655815

#### Phone

+98 21 8865 2343

#### Fax

+98 21 8820 8678

#### Email

info@hezareh-co.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Hezareh Sevom Futuristic Pharmacist

#### Full name of responsible person

Tayebeh Ghari

#### Street address

Unit 4, No 81, Babak Bahrami st, After Zafar st, Tehran, Iran.

#### City

Tehran

#### Province

Tehran

#### Postal code

1968655815

#### Phone

+98 21 8865 2343

#### Email

info@hezareh-co.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Hezareh Sevom Futuristic Pharmacist

### 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

Other

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Alborze University of Medical Sciences, School of Pharmacy

#### Full name of responsible person

Faranak Salmannejad

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

Alborze School of pharmacy, near Bahonar Hospital, Vali-e-asr st, Shora Blv, Karaj.

#### City

Karaj

#### Province

Alborz

#### Postal code

3154686689

#### Phone

+98 26 3256 7175

#### Email

salmannejad.f@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Alborze University of Medical Sciences, School of

Pharmacy  
**Full name of responsible person**  
Faranak Salmannejad  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Alborze School of pharmacy, near Bahonar Hospital,  
Vali-e-asr st, Shora Blv,Karaj.  
**City**  
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**Province**  
Alborz  
**Postal code**  
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salmannejad.f@gmail.com

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Alborze University of Medical Sciences, School of  
Pharmacy  
**Full name of responsible person**  
Faranak Salmannejad  
**Position**  
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**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Alborze School of pharmacy, near Bahonar Hospital,  
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**City**  
Karaj  
**Province**

Alborz  
**Postal code**  
3154686689  
**Phone**  
+98 26 3256 7175  
**Email**  
salmannejad.f@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data is potentially shareable after unidentified  
individuals.

### When the data will become available and for how long

from 2021

### To whom data/document is available

People working in industry and academia

### Under which criteria data/document could be used

Specify the exact purpose of the requested  
documentation

### From where data/document is obtainable

Sending email to info@hezareh-co.com - Sending fax to  
00982188208678 - Calling to 00982188652343 -  
Responsible person: Tayebeh Ghari

### What processes are involved for a request to access data/document

Sending email to info@hezareh-co.com/ request  
evaluation/sending data

### Comments