Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence Study of sustained release memeantin 21 mg capsule manufactured by Tasinm Pharmaceutical and Namenda 21 capsule manufactured by Forest Laboratory in 24 Healthy Volunteers under fasting condition

Protocol summary

Study aim
Comparison of the bioavailability of memantin sustained release capsules after a single dose of 21mg, manufactured by Tasnim Pharmaceutical and Forest Laboratory .

Design
The study is a cross-over double-blind study. 24 healthy volunteers using the random option in excel software will be assigned a code, and depending on the code, the first half will receive the test, and the second half will receive reference drugs. In each phase of the study, 15 blood samples will be received from the individual.

Settings and conduct
On the day of sampling, after 10 hours of fasting, the volunteers come to Kharazmi Plasma Center in Islamshahr (No. 13, 1st Shehamat Alley, Ali Ibn Abitalib St., Namaz Square,) and receive one capsule of the test or reference drug with 240 ml of water and blood samples are taken at 0, 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 24, 48, 72 hours after drug administration, after plasma separation, the samples were transferred to a -70 freezer and finally the concentration of drug in plasma will be determined according to the LCMSMS method.After a 3-weeks wash out period, the process of drug administration is done vise versa.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Healthy adult male (18 - 55 yrs) and sterile or post menopausal female subjects, Body weight must be ≥50 kg and <100 kg, with a body mass index (BMI) >18 but <33.Laboratory parameter values must fall within the normal range Exclusion criteria: history of allergic reaction to memantion. Smokers or user of tobacco products , history of arrhythmia.

Intervention groups
Comparing the blood concentration of memantin if Tasnim Pharmaceutical and Namenda manufactured by Forest Laboratory

Main outcome variables
Plasma concentration caused by test and reference drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220209053979N13**
Registration date: **2023-12-09, 1402/09/18**
Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**
Update count: **0**

Registration date
2023-12-09, 1402/09/18

Registrant information

Name
Roya Talari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8880 0892

Email address
talari_r@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-14, 1402/09/23

Expected recruitment end date
2024-01-04, 1402/10/14

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Bioequivalence Study of sustained release memeantin 21 mg capsule manufactured by Tasinm Pharmaceutical and Namenda 21 capsule manufactured by Forest Laboratory in 24 Healthy Volunteers under fasting condition

Public title
Bioequivalence of sustained release memeantin 21 mg capsule manufactured by Tasinm Pharmaceutical and namenda manufactured by Forest Laboratory
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy male or female volunteers Body mass index (BMI) between 18 - 30 Volunteers who are willing to sign an informed consent form
Exclusion criteria:
History of allergic reaction to memantin or formulation components Taking any type of medicine in the 14 days before the start of the study Participation in any type of clinical study in the last month History of arrhythmia
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **15**
5 mililitr blood sample is taken from each volunteers
Randomization (investigator's opinion)
Randomized
Randomization description
Using the rand option of the Excel software, the candidates are divided into two groups, and half of them will receive numbers 1-12 and get the test drug, and the other half will receive numbers 13-24 and will take the reference drug.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drug (test or reference drug) is removed from the original packaging the day before the study and packaged in small disposable containers. Therefore, it is not in the original packaging and also the visual appearance and size of the test and reference capsules are the same , none of the volunteer nor the prescriber know which drug is being administered. The relevant code is also written on the sample collecting tubes of each volunteer, neither the analyzer knows the test or reference drug sample is analyzing.
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 Science
Street address
Tehran University of Medical Science, 16 Azar St.,
City
Tehran
Province
Tehran
Postal code
1417713135
Approval date
2023-11-25, 1402/09/04
Ethics committee reference number
IR. TUMS. TIPS. REC. 1402. 110

Health conditions studied

1

Description of health condition studied
A crossover bioequivalence study in 24 healthy volunteers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration time profile, maximum plasma concentration, AUC
Timepoint
0, 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 24, 48, 72 h
Method of measurement
Liquid chromatography with mass spectrophotometry

Secondary outcomes

1

Description

Calculation of pharmacokinetic parameters like Cmax, AUC of test and reference drug.

Timepoint

Same as primary outcome

Method of measurement

Pharmacokientic parameters are calculated by excel.

Intervention groups

1

Description

Intervention group: Oral administration of one memantin 21 mg capsule manufactured by Tasnim Pharmaceutical to 12 healthy volunteers under fasting condition with 240 ml of water. Then 15 blood samples are taken from volunteers at 0, 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 24, 48, 72 hours after drug administration. In the second phase after a wash out period of 3 weeks , this group take Forest Laboratory medicine and blood samples are taken at the same times

Category

Other

2

Description

Intervention group: Oral administration of one memantin 21 mg capsule manufactured by Forest Laboratory to 12 healthy volunteers under fasting condition with 240 ml of water. Then 15 blood samples are taken from volunteers at 0, 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 24, 48, 72 hours after drug administration. In the second phase after a wash out period of 3 weeks , this group take Tasnim Pharmaceutical medicine and blood samples are taken at the same times

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kharazmi plasma center

Full name of responsible person

Sara Solgi

Street address

No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,

City

Islamshahr

Province

Tehran

Postal code

3313679886

Phone

+98 21 5669 4726

Email

Info@kpcir.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tasnim Pharmaceutical

Full name of responsible person

Dr. Nami Moghadam

Street address

Tasnim Building, No. 3, 14th East Street, Beyhaqi St., Argentina Square

City

Tehran

Province

Tehran

Postal code

1517615814

Phone

+98 21 8877 2072

Fax

+98 21 8877 2348

Email

info@tasnimpharma.com

Web page address

http://tasnimpharma.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tasnim Pharmaceutical

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

Kharazmi Plasma Center

Full name of responsible person

Roya Talari

Position

Executer

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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
The bioequivalence study data is completely confidential and according to the contract with Shafa Pharmaceutical Company, it should not be published anywhere.

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