Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Bioequivalance study of Tramadole 100 mg Tablets manufactured by Shahr Daru pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Reference Tablets

Protocol summary

Study aim
Comparing pharmacokinetics parameters of Tramadol 100 mg Tablets manufactured by Shahr daru pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Reference Tablets

Design
Bioequivalance study insists of one 24 healthy volunteers group. This group itself randomly divided to two 12 volunteers sub-groups. The first sub-groups administrated reference drug and the second sub-groups administrated generic or test drugs. The bioequivalance study is performed as cross over double blind within 1-2 weeks.

Settings and conduct
Bioequivalance Tramadol 100 mg study will be performed under physician since 7 Am until 7 Pm. This study is carried out as a cross over double blind investigation. The blind person include volunteers, administrator and analyst.

Participants/Inclusion and exclusion criteria
Acceptance criteria: 1- Healthy liver 2- Healthy kidney 3- Volunteers should not be too fat or too thin and their weight index should be in the appropriate range
Rejection criteria: 1- Smokers and pregnancy.

Intervention groups
Intervention consists of administration of one Tramadol 100 mg tablet of Shahr daru company as TEST PRODUCT to the first twelve group in this cross-study and simultaneously administration of tablets as REFERENCE PRODUCT to the second twelve group as control group.

Main outcome variables
Plasma concentration of Tramadol 100 mg is the main consequence, its concentration at Tmax reaches about 350 ng/mL and its measurement range is from 10ng / mL to 1000ng / mL.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200513047423N7**
Registration date: **2022-04-06, 1401/01/17**
Registration timing: **prospective**

Last update: **2022-04-06, 1401/01/17**
Update count: **0**

Registration date
2022-04-06, 1401/01/17

Registrant information

Name
Amir Mehdizadeh

Name of organization / entity
Ofogh pajo

Country
Iran (Islamic Republic of)

Phone
+98 21 6673 8727

Email address
ofoghfarmed.lab@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-27, 1401/03/06

Expected recruitment end date
2022-06-03, 1401/03/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Bioequivalance study of Tramadole 100 mg Tablets manufactured by Shahr Daru pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Reference Tablets

Public title
Bioequivalance study of Tramadole 100 mg Tablets

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy liver Healthy kidney Volunteers should not be too fat or too thin and their weight index should be in the appropriate range

Exclusion criteria:
Out of age ranges smoking pregnancy

Age
From **18 years** old to **50 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: **1**
Each volunteers has been administrated one reference drug and next time test drugs

Randomization (investigator's opinion)
Randomized

Randomization description
We designate to 24 healthy volunteers one number between 1 and 24. Extraction of 12 numbers is carried out using https://kitset.ir/numbers/random#random-number-form. These first 12 random numbers create the first group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The main investigator creates a table using randomization and divides 24 healthy volunteer in 2 groups which only he knows the details of group. Test and reference drugs are packaged in special envelopes that administrator and volunteers are blinded regarding to the kind of drugs. Volunteers, administrator (health care professional) and analyst are blinded regarding to reference and test drugs.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of school and Nurcing & midwiferi-shahid beheshti univercity of medical

Street address
No.65, Razi Ave, Enghelab Ave

City
Tehran

Province
Tehran

Postal code
1133713144

Approval date
2022-02-22, 1400/12/03

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.312

Health conditions studied

1

Description of health condition studied
Bioequivalance Tramadole 100 mg

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
plasma concentration changing after administration of Tramadole 100 mg tablet.Plasma concentration of Tramadole at Tmax reaches about 350 ng/mL and its measurement range is from 10ng / mL to 1000ng / mL

Timepoint
Initial blood sampling is performed before drug administration to obtain blank plasma chromatogram of each volunteers. Hence the Tmax of Tramadole is between 1 and 2 hours, so it is needed to have 5 blood sampling before Tmax. This period of time is called absorption phase. In the elimination phase (after Tmax) blood sampling carry out each hours.

Method of measurement
In this study, the variable is plasma concentration of Tramadole. High performance liquid chromatography is used to determine the concentration of Tramadole in plasma.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One Tramadole 100 mg tablet manufactured by Shahr daru company (Test drug) is administrated to each of 12 healthy volunteer of group 1
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Ofoqh pharmed
Full name of responsible person
Dr Amir mehdizadeh
Street address
No. 65, Razi Ave, Enqhelab Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrdaru Pharmaceutical Co.
Full name of responsible person
Mr. Mohammad Sepasi Ashtiani
Street address
No. 1, Corner of Shateri Alley, Jomhuri Koi Saleh St., Hafez St., Tehran
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Postal code
1135653133
Phone
+98 21 6670 4814
Email
info@shahredaru.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrdaru Pharmaceutical Co.
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
Ofoqh pharmed labratory
Full name of responsible person
Dr Amir mehdizadeh
Position
Responsible pharmacist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Position
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Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Demography tables of volunteers including group 1 and 2 have been shared in bioequivalence report.

When the data will become available and for how long
The results of bioequivalence study of Tramadole tablets will be shared after accepting by Iranian food and drug organization.

To whom data/document is available
The results of bioequivalence study of Tramadole tablets will be accessed by expert by Iranian food and drug organization and financial supporter

Under which criteria data/document could be used
To promotion of result of investigation, the results will be shared with eager

From where data/document is obtainable
1-Iranian food and drug organization 2- Ofogh pharmed research laboratory

What processes are involved for a request to access data/document
To complied of educational filed of eager to result of investigation.

Comments