

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Bioequivalence 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

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

Settings and conduct

Bioequivalence 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

Ofoh 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

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

Public title

Bioequivalence study of Tramadol 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 Nursing & midwifery-shahid beheshti university 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

Bioequivalence Tramadol 100 mg

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

plasma concentration changing after administration of Tramadol 100 mg tablet. Plasma concentration of Tramadol at T_{max} 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 T_{max} of Tramadol is between 1 and 2 hours, so it is needed to have 5 blood sampling before T_{max}. This period of time is called absorption phase. In the elimination phase (after T_{max}) blood sampling carry out each hours.

Method of measurement

In this study, the variable is plasma concentration of Tramadol. High performance liquid chromatography is used to determine the concentration of Tramadol 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

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a_mehdizadeh@gmail.com

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

City

Tehran

Province

Tehran

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

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Farzad kobarfard

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Dr Amir mehdizadeh

Position

Responsible pharmacist

Latest degree

Ph.D.

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 Tramadol tablets will be shared after accepting by Iranian food and drug organization.

To whom data/document is available

The results of bioequivalence study of Tramadol 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