Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

In- Vivo Bioequivalence study of Oxycodone tablet 40 mg Faran shimi (FAROXY® ER 40mg Tab.) with brand drugs (OXYCONTINE® ER 40 mg Tab.,Purdue Pharma LP, UK) in Iranian healthy volunteers

Protocol summary

Study aim

In- Vivo Bioequivalence study of Oxycodone tablet 40 mg Faran shimi (FAROXY® ER 40mg Tab. with brand drugs (OXYCONTINE® ER 40 mg Tab.,Purdue Pharma LP, UK) in Iranian healthy volunteers.

Design

Single dose, randomized, two sequences, two period crossover with a washout period

Settings and conduct

This study will be conducted in single dose, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of 72 hours.The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form.In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney and liver disease or dis functions with both sex (male&female). The ages and BMIs of participant should be in the range of 18-60 and 18-28 respectively

Intervention groups

Intervention group Single dose Oxycodone tablet 40 mg Faran shimi (FAROXY® ER 40mg Tab.) with brand drugs (OXYCONTINE® ER 40 mg Tab.,Purdue Pharma LP, UK

Main outcome variables

Determination of blood drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N32**
Registration date: **2021-06-13, 1400/03/23**
Registration timing: **prospective**

Last update: **2021-06-13, 1400/03/23**
Update count: **0**

Registration date

2021-06-13, 1400/03/23

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-30, 1400/04/09

Expected recruitment end date

2022-01-29, 1400/11/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
In- Vivo Bioequivalence study of Oxycodone tablet 40 mg Faran shimi (FAROXY® ER 40mg Tab.) with brand drugs (OXYCONTINE® ER 40 mg Tab.,Purdue Pharma LP, UK) in Iranian healthy volunteers

Public title
In-vivo Bioequivalence Test of FAROXY® tablet with brand OXYCONTIN drugs (Purdue Pharma LP, UK

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
General health Body mass index(18-28) Informed consent Age(18-60)
Exclusion criteria:
Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked
- Participant

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation law will be used for randomization of volunteers in this study. This method represents a large block for the total sample size, which means that a balance in the number of people assigned to each group will be obtained at the end of the study. By this method, sequences 1(subjects no: 1-12) and sequences 2 (subjects no: 13-24) will be selected by using a simple paper lottery. the first and second 12 persons will be considered as sequence 1 (Group A) and sequence 2 (Group B) respectively.

Blinding (investigator's opinion)
Single blinded

Blinding description
Candidates are not aware of the test drug or brand name. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. OXYCONTIN and OXYCONTIN are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Tabriz University of Medical Sciences
Street address
Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766

Approval date
2021-05-16, 1400/02/26

Ethics committee reference number
IR.TBZMED.REC.1400.160

Health conditions studied

1

Description of health condition studied
In this study, the disease is not examined. Subject bioequivalence test and reference tablets OXYCONTIN studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Determination of blood drug concentration

Timepoint
Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours After prescribing the tablet.

Method of measurement
High Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: : Intervention group received one test drug table(FAROXY® ER 40mg Faran Shimi). Blood

samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of FAROXY in blood samples was measured by liquid chromatography with mass spectroscopy detector

Category

Treatment - Other

2

Description

Control group: Control group: received one test drug table(OXYCONTINE® ER 40 mg Tab.,Purdue Pharma LP, UK). Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of OXYCONTINE in blood samples was measured by liquid chromatography with mass spectroscopy detector

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Simin Baspar Teyf Gostar Company

Full name of responsible person

Javad Shokri

Street address

No.48, Ferdos Street 48

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5167874434

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Email

Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pharan shimi Pharmaceutical Company

Full name of responsible person

Sahar Pedram

Street address

No. 3, Kaveh Dedend, Entezami St., Attar Square, Attar St, Tehran, Iran

City

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Province

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Postal code

6583117698

Phone

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Email

info@faranshimi.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pharan shimi 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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

Professor

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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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
These date are as secure between researcher and related industries

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
Yes - There is a plan to make this available

Title and more details about the data/document
Only protocol and methods of study are sharable

When the data will become available and for how long
Only protocol and methods of study are sharable

To whom data/document is available
Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used
Projects information's for any publications is not allowed.

From where data/document is obtainable
Projects information's for any publications is not allowed.

What processes are involved for a request to access data/document
This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the

Comments