Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative bioequivalence study of Alprazolam 0.5 mg Tablet of Karen Pharma and Food Supplement Co. and Xanax® of Pfizer as reference in 24 healthy male under fasting conditions

Protocol summary

Study aim

Comparing the pharmacokinetics and in-vivo parameters of Alprazolam 0.5 mg Tablet as a test with Xanax® 0.5 mg Tablet as a reference product to evaluate the bioequivalence.

Design

Non blinded, randomized, crossover in-vivo bioequivalence study in 24 healthy males under fasting conditions. Block randomization by https://www.sealedenvelope.com/simple-randomiser/v1/lists for a treatment sequence of Test/Reference or Reference/Test will be used.

Settings and conduct

In each period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran) according to a prepared block randomization schedule without blinding. 16 blood samples were collected during 72 hours post intervention.

Participants/Inclusion and exclusion criteria

Inclusive Criteria: Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during clinical examination and laboratory evaluations.
Exclusive Criteria: Subjects with known allergy to the products tested. Subjects with narrow-angle glaucoma and CYP3A4 inhibitors.

Intervention groups

Group 1: Alprazolam 0.5 mg Tablet, produced by Karen is the test product. In each period, 12 of 24 subjects will take a single oral dose of this product. After 7-day wash-out period, the Xanax 0.5 mg Tablet will be given to these subjects.Group 2: Xanax 0.5 mg Tablet, produced by Pfizer is the reference product. In each period, 12 of 24 subjects will take a single oral dose of this product. After 7-day wash-out period the Alprazolam 0.5 mg Tablet, produced by Karen will be given to these subjects.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N43**
Registration date: **2023-04-19, 1402/01/30**
Registration timing: **prospective**

Last update: **2023-04-19, 1402/01/30**
Update count: **0**

Registration date

2023-04-19, 1402/01/30

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

Phone

+98 21 6600 7026

Email address

info@tavaninstitute.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-24, 1402/02/04

Expected recruitment end date

2023-05-08, 1402/02/18

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

Scientific title
Comparative bioequivalence study of Alprazolam 0.5 mg Tablet of Karen Pharma and Food Supplement Co. and Xanax® of Pfizer as reference in 24 healthy male under fasting conditions

Public title
Comparative in vivo evaluation of 2 Alprazolam 0.5 mg Tablet formulations.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy subjects (male) between 20-45 years of age and Body Mass Index (BMI) within 15% of normal range values between 18.5-30 (inclusive), calculated as Kg/m2. Subjects with no significant diseases or abnormal findings during laboratory evaluations and clinical examination. Subjects with normal vital signs. Subjects who agree with patient consent form.
Exclusion criteria:
Subjects with known allergy to the products tested. Subjects who have narrow angle glaucoma or are taking strong CYP3A inhibitors. History of cardiovascular, kidney, hepatic, muscular, metabolic, gastrointestinal (including constipation), neurologic, endocrine, hematopoietic (any kind of anemia), asthma, mental or organic disease. Subjects suffering from muscular trauma 21 days before the beginning of the study. Consumption of caffeine-containing products from 24 hour before dosing through 24 hour after administration. Any clinically significant illness during the 4 weeks prior to the first study drug administration. Hypotension (systolic blood pressure ≤90 millimeter Hg (mmHg) or diastolic blood pressure ≤60 mmHg) or hypertension (systolic blood pressure ≥130mmHg or diastolic blood pressure ≥90 mmHg). Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Recent use of concomitant medication (prescription or over-the-counter) that could increase the risk of bleeding, or influence alprazolam pharmacokinetics. History of alcohol or drug abuse. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study.
Age
From **20 years** old to **45 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked
No information

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization schedule will be generated with https://www.sealedenvelope.com/simple-randomiser/v1/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer's number (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer. This is a non-blinded study design.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medica
Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2023-01-24, 1401/11/04
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.234

Health conditions studied

1

Description of health condition studied
Sedative, hypnotic, or anxiolytic related disorders
ICD-10 code
F13
ICD-10 code description
Sedative, hypnotic, or anxiolytic related disorders

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)
Timepoint
Before intervention and then at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 12, 24, 48 and 72 hours post intervention in each period
Method of measurement
using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
Before intervention and then at 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 12, 24, 48 & 72 hours post intervention in each period
Method of measurement
using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description
Intervention group 1: Alprazolam 0.5 mg tablet, produced by Karen is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects.
Category
Treatment - Drugs

2

Description
Intervention group: Alprazolam 0.5 mg tablet produced by Pfizer is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 1 will be given to these subjects.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hakim Farabi Clinic
Full name of responsible person
Ebrahim Siahpoosh
Street address
No. 57, Shemshad alley, Sallor city
City
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Province
Tehran
Postal code
4635314588
Phone
+98 21 9253 5647
Email
partochem@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karen Pharma and Food Supplement Co.
Full name of responsible person
Zahra Mortazavi
Street address
No: 3, Western Nahid st. Africa Blvd.
City
Tehran
Province
Tehran
Postal code
۱۴۵۹۹۶۵۲۰۴
Phone
+98 21 2620 4283
Email
info@karenpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karen Pharma and Food Supplement 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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Noor Research & Development Institute
Full name of responsible person
Ali Aghaei
Position
Master
Latest degree

Master

Other areas of specialty/work

Pharmacy

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Person responsible for scientific inquiries

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Seyed Mohsen Foroutan

Position

Principal investigator

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Full name of responsible person

Ali Aghaei

Position

Master

Latest degree

Master

Other areas of specialty/work

Pharmacy

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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

It's not specified yet.

Study Protocol

Undecided - It is not yet known if there will be 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