Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Relative bioavailability comparison of Alprazolam 0.5mg tablet formulations in healthy adult male volunteers under fasting conditions

Protocol summary

Study aim

Relative bioavailability comparison of Alprazolam 0.5mg tablet in healthy adult male volunteers

Design

Double-Blind,Cross-over, two sequences, and two-period study and outcome assessment, Twenty four subjects A washout period of 7 days Each subject was considered as his own control.

Settings and conduct

Blood sampling is done in the hospital.Volunteers and clinical caregivers are blind. The code of the volunteers,the intervention and control group is placed in an envelope by the researcher and is distributed randomly on the day of the experiment without informing the volunteer and the clinical caregiver.

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Participants/Inclusion and exclusion criteria

Inclusion Criteria: Gender: Male Age:18 and 50 years The volenteer is willing to do the study and can sign and submit the informed consent form The candidate is fully present during the study Normal clinical and laboratory results Exclusion Criteria: History of allergy or allergy to alprazolam Any history of hypersensitivity or intolerance that, reduces the safety of the study volunteers Any history of chronic infectious disease, systemic defects, or organ dysfunction Gastrointestinal disease, malabsorption in the last year A history of a medical problem over the last year that required medication or hospitalization Drugs that significantly induce or inhibit drug-metabolizing enzymes that be used within 30 days prior to administration Receive any medication from previous research studies within 30 days prior to the current study Donation or loss of significant amounts of blood within 30 days prior to current study Smokers or addicts

Intervention groups

Raha Pharmaceutical Company-Alprazolam 0.5mg tablet
Pfizer Pharmaceutical Company-Alprazolam 0.5mg tablet

Main outcome variables

Confirmation or non-confirmation of the bioequivalance of the sample and reference drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201212049683N1**
Registration date: **2021-01-03, 1399/10/14**
Registration timing: **prospective**

Last update: **2021-01-03, 1399/10/14**
Update count: **0**

Registration date

2021-01-03, 1399/10/14

Registrant information

Name

Akram Sharifian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7117

Email address

dash481@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Relative bioavailability comparison of Alprazolam 0.5mg tablet formulations in healthy adult male volunteers under fasting conditions

Public title
Relative bioavailability comparison of Alprazolam 0.5mg tablet formulations

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Gender: Male Age between 18 and 50 years The volenteer is willing to do the study and can sign and submit the informed consent form The candidate is fully present during the study and according to the consent form, believes in and adheres to the implementation of the study protocol Candidate must have a specific place of residence and a landline Normal clinical and laboratory results

Exclusion criteria:
History of allergy or allergy to alprazolam Any history of hypersensitivity or intolerance that, in the opinion of the researcher, reduces the safety of the study volunteers Any history of chronic infectious disease, systemic defects, or organ dysfunction Presence of gastrointestinal disease or a history of malabsorption in the last year A history of a medical problem over the last year that required medication or hospitalization Drugs that significantly induce or inhibit drug-metabolizing enzymes that be used within 30 days prior to administration Receive any medication from previous research studies within 30 days prior to the current study Donation or loss of significant amounts of blood (480 ml or more) within 30 days prior to current study Smokers or addicts

Age
From **18 years** old to **50 years** old

Gender
Male

Phase
Bioequivalence

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is done individually, using a sealed envelope. The code of the volunteers and the Test and Control group is placed in the envelope by the researcher and distributed randomly on the day of the experiment without the knowledge of the volunteer and the clinical caregiver.

Blinding (investigator's opinion)
Double blinded

Blinding description
Volunteers, project partners, physicians,nurses, and those responsible for the initial data collection and analysis of data, are only unaware of the date of receipt of the sample or reference drug. Volunteers code and and tha date of receipt of the sample or reference is determined by the researcher. Volunteers, project partners, physicians , nurses, and those responsible for the initial data collection and analysis of data, are aware of the type of drug and its manufacturer.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Building No. 4, Isfahan University of Medical Sciences, Hezar Jarib Ave.

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Isfahan

Province
Isfehan

Postal code
۷۳۴۶۱-۸۱۷۴۶

Approval date
2020-11-18, 1399/08/28

Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.596

Health conditions studied

1

Description of health condition studied
Relative bioavailability

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Comparison of Cmax, Tmax and AUC and comparison of blood profiles of the two drugs

Timepoint
0, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 6, 8, 10, 24, 36h

Method of measurement
HPLC analysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Two tablets of Raha pharmaceutical company alprazolam 0.5 mg simultaneously
Category
Other

2

Description
Intervention group 2: Two tablets of Pfizer pharmaceutical company alprazolam 0.5 mg simultaneously
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Milad hospital
Full name of responsible person
Dr Akram Sharifian
Street address
Simin intersection, Janbazan St., Shahid Bakhshi St., Milad Hospital
City
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8179645574
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+98 31 3777 4009
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dash481@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Raha Pharmaceutical Company
Full name of responsible person
Dr Gholamreza Akhavan Farid
Street address
No.11, Sofeh Ind. Zone, 7th km of Shiraz Road, Isfahan
City
Isfahan
Province
Isfehan
Postal code
81745-567
Phone
+98 31 3654 0659
Email
qa@rahapharm.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Raha 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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Akram Sharifian
Position
PHD student of pharmaceutical science
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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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)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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