

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparative bioequivalence study of the Azithromycin 500 mg, tablet manufactured by Nikasa Pharmed Company

Protocol summary

Study aim

Examining the bioequivalency of domestically produced Azithromycin tablet formulations with brand samples (Pfizer®)

Design

A single-group, not blinded, not randomized, bioequivalence clinical trial on 24 healthy volunteers.

Settings and conduct

En The number of 24 healthy men in the age range of 18-60 years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification. One tablet is taken fasting and blood is taken at 18 times point. One week later, the process is repeated for the brand medicine

Participants/Inclusion and exclusion criteria

The weight range of participating candidates should be between 60-100 kg. All candidates must be non-smokers. Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose. Volunteers who have agreed to an informed consent form.

Intervention groups

After taking a Sitagliptin Azithromycin tablet from domestic company, 3 milliliters of blood will be collected from the volunteer in 18 times intervals for 72 hours. Three weeks later, the process is repeated for a brand sample tablet. The drug concentration is measured in plasma.

Main outcome variables

Studying the Drug pharmacokinetic parameters including measuring the plasma concentrations of drugs for brand and test products, determining the desired and

important pharmacokinetic parameters in bioequivalence studies, AUCs, T_{max}, C_{max}, T_{1/2}

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130313012810N15**

Registration date: **2023-10-09, 1402/07/17**

Registration timing: **prospective**

Last update: **2023-10-09, 1402/07/17**

Update count: **0**

Registration date

2023-10-09, 1402/07/17

Registrant information

Name

Hamed Hamishehkar

Name of organization / entity

Drug Applied Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1336 3311

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-01, 1402/08/10

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of the Azithromycin 500 mg, tablet manufactured by Nikasa Pharmed Company

Public title

Comparative bioequivalence study of the Azithromycin 500 mg, tablet manufactured by Nikasa Pharmed Company

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

The weight range of participating candidates should be between 60-100 kg Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw

Exclusion criteria:

History of allergic or adverse reaction to Azithromycin or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s)

Age

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

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 24 volunteers were randomly divided into two groups of 12 test (A) and reference (B) drug recipients by Excel software, then in the second phase, groups A and B will be cross-referenced to the test and drug recipients.

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 Tabriz University of Medical Sciences

Street address

Daneshghah St. Drug Applied Research Center

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Approval date

2023-09-04, 1402/06/13

Ethics committee reference number

IR.TBZMED.REC.1402.429

Health conditions studied**1****Description of health condition studied**

Bioequivalence study in healthy volunteers

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Plasma concentration of the drug

Timepoint

En 17 sampling time included pre-dose (time 0) and at the following hours post-dose: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24, 48 and 72 h

Method of measurement

Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: This study examines the bioequivalence of Azithromycin tablets produced by a domestic company with a foreign brand sample. We have only one intervention group and there is no control group. The intervention group, which includes healthy, fasting male volunteers, will receive a single dose, 500 mg tablet manufactured by the pharmaceutical company Nikasa Pharmed and Pfizer brand, in two 72-hour periods with an interval of two week, on the day of the study. And in 18 different time periods up to 72 hours after taking the medicine, blood samples will be taken from the volunteers in the amount of 3 ml each time, that is, a total of 54 ml within 72 hours. The training that will be given to the volunteers includes avoiding the consumption of drinks containing alcohol and xanthine and other interfering drugs in the prescription drug from 48 hours before the start of the study until the end of the study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug Applied Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nikasa Pharmed Company

Full name of responsible person

Pardis Kalantarian

Street address

Unit 13., 5th Floor., No. 53 Golab Building., Shahid Golab Boulevard, Jenah Highway, Tehran

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1451818756

Phone

+98 21 9103 0103

Email

info@nikasapharmed.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nikasa Pharmed 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

Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

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

No - There is not a plan to make this available