Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparative bioequivalence study of the Pazopanib 200-mgTablets manufactured by Noavaran Daroui Kimia Company

Protocol summary

Study aim

Examining the bioequivalency of domestically produced Pazopanib tablet formulations with brand samples(Votrient ®)

Design

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

Settings and conduct

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 16 times point. Three 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 Pazopanib 200-mg tablet from domestic company, 3 milliliters of blood will be collected from the volunteer in 16 times intervals for 72 hours. Three week 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, Tmax, Cmax, T1/2 and appropriate statistical analysis of the data

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130313012810N13**
Registration date: **2023-09-12, 1402/06/21**
Registration timing: **prospective**

Last update: **2023-09-12, 1402/06/21**
Update count: **0**

Registration date

2023-09-12, 1402/06/21

Registrant information

Name

Hamed Hamishehkar

Name of organization / entity

Drug Applied Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 3311

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-21, 1402/06/30

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of the Pazopanib 200-mgTablets manufactured by Noavaran Daroui Kimia Company

Public title
Comparative bioequivalence study of the Pazopanib 200-mgTablets manufactured by Noavaran Daroui Kimia Company
Purpose
Other
Inclusion/Exclusion criteria
Inclusion 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 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 Pazopanib or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Smokers Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s) Due to the possibility of QT prolongation complications, volunteers with a family history of heart diseases, especially rhythm disorders, are excluded from the study.
Age
From **18 years** old to **60 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
N/A
Randomization description
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
2023-08-28, 1402/06/06
Ethics committee reference number
IR.TBZMED.REC.1402.401

Health conditions studied

1

Description of health condition studied
-
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of the drug
Timepoint
16 sampling time till 72 h
Method of measurement
Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Intervention group 1 consists of healthy and fasting male volunteers who will receive a single dose of 200 mg pazopanib tablets manufactured

by the domestic pharmaceutical company of Noavaran Daroui Kimia in a period of 72 hours, on the day of the start of the study, and in 16 different time periods up to 72 hours after taking the drug, blood samples will be taken from the volunteers in the amount of 3 ml each time, that is, a total of 48 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

Other

2

Description

Intervention group 2: Intervention group 2 includes male volunteers, healthy and fasting, who will receive a single dose of pazopanib with a dose of 200 mg manufactured by Novartis pharmaceutical company in a period of 72 hours, on the day of the start of the study, and in 16 different time periods up to 72 hours after taking the drug, blood samples will be taken from the volunteers in the amount of 3 ml each time, that is, a total of 48 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

KIMIA Noavaran Daroui

Full name of responsible person

Mitra Movahedian

Street address

No. 1462, Jalal-Al-Ahmad Highway, Karghar Shomali

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Tehran

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1439955991

Phone

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Email

info@kimia-pharma.co

Grant name

Grant code / Reference number

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

Yes

Title of funding source

KIMIA Noavaran Daroui

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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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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