# 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**

hamishehkar.hamed@gmail.com

**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

**Street address**

Drug Applied Research Center, Tabriz University of Medical Sciences

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51656-65811

**Phone**

+98 41 3336 3311

**Email**

hamishehkar.hamed@gmail.com

## 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955991

**Phone**

+98 21 8801 2946

**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

**Street address**

Drug Applied Research Center, Tabriz University of Medical Sciences

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51656-65811

**Phone**

+98 41 3336 3181

**Fax**

+98 41 3336 3311

**Email**

hamishehkar.hamed@gmail.com

**Web page address**

http://darc.tbzmed.ac.ir/

## Person responsible for scientific 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

**Street address**

Drug Applied Research Center, Tabriz University of Medical Sciences

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51656-65811

**Phone**

+98 41 3336 3181

**Fax**

+98 41 3336 3311

**Email**

hamishehkar.hamed@gmail.com

**Web page address**

http://darc.tbzmed.ac.ir/

## Person responsible for updating data

**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

**Street address**

Drug Applied Research Center, Tabriz University of Medical Sciences

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51656-65811

**Phone**

+98 41 3336 3181

**Fax**

+98 41 3336 3311

**Email**

hamishehkar.hamed@gmail.com

**Web page address**

http://darc.tbzmed.ac.ir/

## 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