

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative bioequivalence study of Ranolazine 1000 mg ER Tablet of Zist Arvand Pharmed. and Ranexa® of Gilead Sciences as reference in 24 healthy male under fasting condition

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Ranolazine 1000 mg ER Tablet formulation as a test product with Ranolazine 1000 mg ER Tablet formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

Non-blinded, randomized, crossover in vivo bioequivalence study on 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test is used.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Noor Research and Development Institute (Tarasht, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy subjects (male) between 18 – 45 years of age. Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18 and 27 (inclusive), calculated as kg/m². Exclusion Criteria: Subjects with known allergy to the products tested. volunteers with associated acute or chronic infections; blood pressure in standing position and after at least 5 minutes of rest, systole less than 90 or more than 140 mmHg and diastole less than 50 or more than 90 mmHg); heart rate less than 50 or more than 90 beats per minute;

Intervention groups

Intervention group 1: Ranolazine 1000 mg ER Tablet, produced by Zist arvand Pharmed. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Ranolazine 1000 mg ER Tablet (Ranexa®), produced by Gilead Sciences is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this

product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N50**

Registration date: **2023-10-18, 1402/07/26**

Registration timing: **prospective**

Last update: **2023-10-18, 1402/07/26**

Update count: **0**

Registration date

2023-10-18, 1402/07/26

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2023-11-25, 1402/09/04

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of Ranolazine 1000 mg ER Tablet of Zist Arvand Pharmed. and Ranexa® of Gilead Sciences as reference in 24 healthy male under fasting condition

Public title
Comparative in vivo evaluation of 2 Ranolazine 1000 mg ER Tablet and Ranexa® 1000 mg ER Tablet formulations.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Healthy subjects (male) between 18 – 45 years of age. Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18 and 27 (inclusive), calculated as kg/m². General laboratory tests of biochemistry, hematology, TSH, HIV, HBs and HCV are performed. Subjects with no significant diseases or abnormal findings during laboratory evaluations and clinical examination. Subjects with normal vital signs.
Exclusion criteria:
Subjects with known allergy to the products tested. volunteers with associated acute or chronic infections; blood pressure in standing position and after at least 5 minutes of rest, systole less than 90 or more than 140 mmHg and diastole less than 50 or more than 90 mmHg); heart rate less than 50 or more than 90 beats per minute; Abnormalities in ECG include: (PR > 210 msec, QRS complex > 120 msec, QTcF > 430 msec); Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period; 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 **18 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 numbers (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.

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 Shahid Beheshti University of Medical Sciences

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2023-10-09, 1402/07/17

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.129

Health conditions studied

1

Description of health condition studied

Angina pectoris

ICD-10 code

I20

ICD-10 code description

Angina pectoris

Primary outcomes

1

Description

Peak Plasma Concentration (C_{max})

Timepoint

19 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 7, 8, 10, 12, 24 and 48 hours after intervention.

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

19 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 7, 8, 10, 12, 24 and 48 hours after intervention.

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description

Intervention group1: Ranolazine 500 mg ER Tablet , produced by Zist arvand Pharmed. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 07-day wash-out period the intervention 2 will be given to these subjects.

Category

Treatment - Drugs

2

Description

Intervention group 2: Ranolazine 1000 mg ER Tablet (Ranexa®), produced by Gilead Sciences is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 07-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

Noor Research & Development Institut(Tavan)

Full name of responsible person

Ali Aghaei

Street address

Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymouri Street, Tarasht.

City

Tehran

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1459926609

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Email

info@tavaninstitute.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zist Arvand Pharmed Ltd.

Full name of responsible person

Dr. Neda Karegar

Street address

Pardis Technology Park, 20th km of Damavand Road (Main Stresst), Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1657163871

Phone

+98 21 7625 0250

Email

info@techpark.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zist Arvand Pharmed Ltd.

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

Contact

Name of organization / entity

Tavan Institute

Full name of responsible person

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

Contact

Name of organization / entity

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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 undetermined 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