Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 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
+98 21 6600 7026

Email address
info@tavaninstitute.ir

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 (Cmax)

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, Teymoury Street, Tarasht.
City
Tehran
Province
Tehran
Postal code
1459926609
Phone
+98 21 6600 4027
Email
info@tavaninstitute.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zist Arvand Pharme 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 Pharme 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
Street address
Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
City
Tehran
Province
Tehran
Postal code

1459926609

Phone
+98 21 6600 4027

Email
partochem@gmail.com

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

Street address
Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.

City
Tehran

Province
Tehran

Postal code
1459926609

Phone
+98 21 6600 4027

Email
mforoutan@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tavan Institute

Full name of responsible person
Ali Aghaei

Position
Master

Latest degree
Master

Other areas of specialty/work
Pharmacy

Street address
Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.

City
Tehran

Province
Tehran

Postal code
1459926609

Phone
+98 21 6600 4027

Email
partochem@gmail.com

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 undetermind 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