

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Pharmacokinetic evaluation and formulation of Ranolazine tablets in comparison with brand drug (RANEXA).

Protocol summary

Study aim

In- Vivo Bioequivalence study of Ranolazine tablets 500mg ARENA (RANOLASE® 500mg) with brand drug (RANEXA® 500mg Menarini O.L.S.A, Luxamburg).

Design

Single dose of ranolazine 500 mg made by Arena company

Settings and conduct

This study will be conducted in two-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of twenty-four hours. The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form. In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will be taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney and liver disease or dis functions with both sex (male&female). The ages and BMIs of participant should be in the range of 18-60 and 18-25 respectively.

Intervention groups

The intervention group receives a single dose of ranolazine 500 mg made by Arena Company. The single-dose control group receives 500 mg of Ranexa drug manufactured by Menarini Company.

Main outcome variables

Determination of blood drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N13**

Registration date: **2020-10-27, 1399/08/06**

Registration timing: **prospective**

Last update: **2020-10-27, 1399/08/06**

Update count: **0**

Registration date

2020-10-27, 1399/08/06

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-25, 1399/10/05

Expected recruitment end date

2021-10-27, 1400/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pharmacokinetic evaluation and formulation of Ranolazine tablets in comparison with brand drug (RANEXA).

Public title
Study of Ranolazine table In-Vivo Bioequivalence in healthy volunteers

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
General health (liver, heart, kidney) Body Mass Index (BMI) between 18-28 Informed consent Age between 18-60 Both male and female
Exclusion criteria:
Smoking Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

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

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Participating candidates are not aware of receiving the test drug or brand drug. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Ranolazine and RANEXA® are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences Ethics Committee
Street address
No.48,Ferdows street, Ferdowsi Sq.

City
Tabriz

Province
East Azarbaijan

Postal code
5167874434

Approval date
2020-06-22, 1399/04/02

Ethics committee reference number
IR.TBZMED.REC.1399.315

Health conditions studied
1
Description of health condition studied
In this study, the disease is not examined. Subject bioequivalence test and reference tablets Ranolase studied.
ICD-10 code
ICD-10 code description

Primary outcomes
1
Description
Determination of blood drug concentration.
Timepoint
Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours.
Method of measurement
Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes
empty

Intervention groups
1
Description
Intervention group: Single dose of Ranolazine tablet 500mg Arena Company as a test product.
Category
Treatment - Drugs

2
Description
Control group: Single dose of Ranolazine 500 mg tablet with brand drugs RANEXA® 500mg Menarini O.L.S.A, Luxembourg.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Simin Baspar Teyf Gostar Company

Full name of responsible person

Javad Shokri

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No.48, Ferdos Street

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Arena life science

Full name of responsible person

Babak Khoeini

Street address

No 17, Golestan 2 , Boustan 3, Velenjak, Tehran-Iran

City

Tehran

Province

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Fax

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Email

info@arenalifescience.com

Web page address

<http://www.arenalifescience.com>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arena life science

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**

Other

Person responsible for general inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

These data are as secure between researcher and related industries.

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

Yes - There is a plan to make this available

Title and more details about the data/document

Only protocol and methods of study are sharable.

When the data will become available and for how long

After finishing of the protocol (Probably 8 months receiving IRCT code)

To whom data/document is available

Pharmaceutical and medical sciences researchers.

Under which criteria data/document could be used

Projects information's for any publications is not allowed.

From where data/document is obtainable

Contact with E-mail of the main researcher.

What processes are involved for a request to access data/document

Personal and academic details and the aim of the request.

Comments