

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Pharmacokinetic assessments of RIFANA® tablet with brand drugs (CUMADIN® 5mg - Bristol-Myers Squibb)

Protocol summary

Study aim

In- Vivo Bioequivalence study of RIFANA tablet 5mg Arena Hayat Danesh with brand drugs (CUMADIN® 5mg, Bristol-Myers Squibb) in Iranian healthy volunteers.

Design

Single dose, randomized, two sequences, two period crossover with a washout period.

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

Intervention group Single dose RIFANA tablet 5mg Arena Hayat Danesh Pharmaceutical Company and Control group Single dose of (CUMADIN® 5mg, Bristol-Myers Squibb).

Main outcome variables

Maximum plasma concentration of the drug, time to reach the maximum plasma concentration, drug

excretion half-life, drug excretion constant

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N17**

Registration date: **2020-12-31, 1399/10/11**

Registration timing: **prospective**

Last update: **2020-12-31, 1399/10/11**

Update count: **0**

Registration date

2020-12-31, 1399/10/11

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

Not yet recruiting

Funding source

Expected recruitment start date

2643-05-05, 2022/02/15

Expected recruitment end date

2643-11-06, 2022/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pharmacokinetic assessments of RIFANA® tablet with brand drugs (CUMADIN® 5mg - Bristol-Myers Squibb)

Public title

In-vivo Bioequivalence Test of RIFANA tablet with brand drugs CUMADIN Made by Bristol-Myers Squibb.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General health Body mass index(18-28) Informed consent Age(18-60)

Exclusion criteria:

Smoking A history of cardiovascular disease A history of liver & kidney disease 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

Candidates are not aware of the test drug or brand name. 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. Eswarfarin and Eswarfarin ® 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

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Tabriz University of Medical Sciences

Street address

Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-12-29, 1399/10/09

Ethics committee reference number

IR.TBZMED.REC.1399.893

Health conditions studied

1

Description of health condition 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

High Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group receives a Single dose Eswarfarin tablet 5mg Arena Hayat Danesh Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group: Control group receives a Single dose CUMADIN® 5mg Bristol-Myers Squibb Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Simin Baspar Teyf Gostar Company

Full name of responsible person

Javad Shokri

Street address

No.48,Ferdos Street

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5167874434

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Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahsa Alizade

Street address

Unit 6, 3rd Floor, No. 16, West Zayandeh Rd Alley,
North Shiraz St., Mollasadra Bank, Tehran, Iran

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Province

Tehran

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1991613857

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info@arenalifescience.com

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

No

Title of funding source

Tabriz University of Medical Sciences

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

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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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 6 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