Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

In- Vivo Bioequivalence study of Teriflunomide tablet 14 mg Aburayhan Pharma with brand drug (AUBAGIO® 14 mg Genzyme, Germany) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Teriflunomide tablet 14 mg Aburayhan Pharma with brand drug (AUBAGIO® 14 mg Genzyme, Germany) 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 one-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of 72 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 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 18-28 respectively

Intervention groups

Intervention group Single dose Teriflunomide tablet 14 mg Aburayhan Pharma Company with brand drugs (AUBAGIO® 14 mg Genzyme, Germany)

Main outcome variables

Determination of blood drug concentration.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N25**
Registration date: **2021-03-11, 1399/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-11, 1399/12/21**
Update count: **0**

Registration date

2021-03-11, 1399/12/21

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

2021-03-10, 1399/12/20

Expected recruitment end date

2022-01-10, 1400/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
In- Vivo Bioequivalence study of Teriflunomide tablet 14 mg Aburayhan Pharma with brand drug (AUBAGIO® 14 mg Genzyme, Germany) in Iranian healthy volunteers.

Public title
In-vivo Bioequivalence Test of Teriflunomide® tablet with brand drugs (AUBAGIO® 14 mg Genzyme, Germany).

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)
Randomized

Randomization description
Random allocation law will be used for randomization of volunteers in this study. This method represents a large block for the total sample size, which means that a balance in the number of people assigned to each group will be obtained at the end of the study. By this method, sequences 1(subjects no: 1-12) and sequences 2 (subjects no: 13-12) will be selected by using a simple paper lottery. the first and second 12 persons will be considered as sequence 1 (Group A) and sequence 2 (Group B) respectively.

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. Tramadol and Tramadol 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
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
2021-03-01, 1399/12/11

Ethics committee reference number
IR.TBZMED.REC.1399.1116

Health conditions studied

1

Description of health condition studied
In this study, the disease is not examined. Subject bioequivalence test and reference tablets Teriflunomide 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 After prescribing the tablet.

Method of measurement
igh Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group received one test drug table(Teriflunomide tablet 14 mg Aburayhan

Pharma). Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Everolimus in blood samples was measured by liquid chromatography with mass spectroscopy detector.

Category

Treatment - Drugs

2

Description

Control group: Control group received one test drug table (AUBAGIO® 14 mg Genzyme, Germany). Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of AFINITOR in blood samples was measured by liquid chromatography with mass spectroscopy detector.

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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Tabriz

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5167874434

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+98 41 3384 2724

Email
Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Aburayhan Pharmaceutical Company

Full name of responsible person
Mortaza Sobhani niya

Street address
Tehran - corner of Tehranpars three ways in front of Shahr Hotel, No. 1

City
Tehran

Province
Tehran

Postal code
1654613111

Phone
+98 21 7770 7173

Email
info@aburaihan.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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Faculty of Pharmacy, Tabriz University of Medical Sciences.

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Javad Shokri

Position
Professor

Latest degree
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Other areas of specialty/work

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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 date 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
Only protocol and methods of study are sharable.

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
By email to the project manager (shokri.j@gmail.com)

What processes are involved for a request to access data/document
This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the

Comments