Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Randomized, single-dose, crossover comparative bioequivalence study of Teriflunomide (Trigio®) 14 mg tablets produced by Zahravi Pharmaceutical Co. versus Aubagio® tablets of Sanofi Genzyme Co. in 14 healthy male under fasting conditions

Protocol summary

Study aim

To demonstrate bioequivalence of single dose test formulation of Zahravi pharmaceutical Co Terifunomide 14 mg tablet versus Aubagio® (Sanofi Genzime Company) as reference.

Design

Single dose, crossover bioequivalence study of Terifunomide 14 mg tablets of Zahravi pharmaceutical Co. (®Trigio) versus Aubagio® (Sanofi Genzime Company) in 14 healthy male under fasting condition.

Settings and conduct

Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. Place for blood and plasma sample analysis: Imam Reza Medical Research and Trainning Hospital. 14 healthy male volunteers received each of two test or reference Terifunomide 14 mg tablets in random sequence according to the randomization schedule. Receiving drug periods were 21 day apart from each other and after the washout period, subjects received the other product. Blood samples were taken from all participants before receiving the drug and 72 hours after that at determined time points for pharmacokinetic evaluations (0, 0.25, 0.5 ، 1, 1.5، 2, 3، 4 ، 5, 6، 8، 12، 24، 48 and 72 hours).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18.5-30. Exclusion criteria: subjects with a history of disease and unusual measures in blood and clinical examination and heavy smokers.

Intervention groups

Intervention group 1 (Test): Terifunomide 14 mg tablet, produced by Zahravi pharmaceutical Co. is the test product. In each period, 7 of 14 subjects will be given single oral dose of this product. Control group 2 (Reference): Aubagio® 14 mg tablets (produced by Sanofi Genzime co.) is the reference product. In each period, 7 of 14 subjects will be given single oral dose of this product.

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N1**
Registration date: **2020-04-18, 1399/01/30**
Registration timing: **prospective**

Last update: **2020-04-18, 1399/01/30**
Update count: **0**

Registration date

2020-04-18, 1399/01/30

Registrant information

Name
Fatima Molavi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized, single-dose, crossover comparative bioequivalence study of Teriflunomide (Trigio®) 14 mg tablets produced by Zahravi Pharmaceutical Co. versus Aubagio® tablets of Sanofi Genzyme Co. in 14 healthy male under fasting conditions

Public title

Bioequivalence study of Teriflunomide 14 mg tablets produced by Zahravi Pharmaceutical Co. versus Aubagio® tablets of Sanofi Genzyme Co. in 14 healthy male under fasting conditions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy subjects with BMI 18.5-30 kg/m2 Not having any abnormal finding in laboratory examination or during physical examination. Not having a history of any significant disease. Subjects who agree with patient consent form.

Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to Ondansetron or any ingredients. Subjects with BP ≤ 9060 mm/Hg or BP ≥ 140/90 mm/Hg Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of TB, epilepsy, asthma (during past 5 years), DM, psychosis or glaucoma. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two week before dosing

Age

From **16 years** old to **60 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

Randomized

Randomization description

Each subject is identified by a number from 1 to 14. This number is allocated according to their entrance to volunteers' list in the screening day. Then, the following randomization table is used according to the crossover design of the study. All participants randomized into two sequences of Test/Reference and Reference/Test products Subjects Dosing Sequence Day 1 Day 22. 1 R/T Reference Test 2 R/T Reference Test 3 R/T Reference Test 4 R/T Reference Test 5 R/T Reference Test 6 R/T Reference Test 7 R/T Reference Test 8 T/R Test Reference 9 T/R Test Reference 10 T/R Test Reference 11 T/R Test Reference 12 T/R Test Reference 13 T/R Test Reference 14 T/R Test Reference.

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

Iran National Committee for Ethics in Biomedical Research

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

01419943471

Approval date

2020-03-16, 1398/12/26

Ethics committee reference number

IR.TBZMED.REC.1398.1316

Health conditions studied

1

Description of health condition studied

Immunomodulatory drug for the treatment of Multiple Sclerosis (MS)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

At 0 (before dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 48 & 72 hour after dosing

Method of measurement

HPLC

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
During 2 months after intervention
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description
Intervention group (Test): Teriflunomide 14 mg tablets, produced by Zahravi pharmaceutical Co. is the test product. In each period, 7 of 14 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group (Reference): Teriflunomide 14 mg tablets (Aubagio®), produced by Sanofi Genzime Company is the reference product. In each period, 7 of 14 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahravi pharmaceutical company
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahravi pharmaceutical company
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
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Hamed Hamishehkar
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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