

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 Genzyme Company) as reference.

Design

Single dose, crossover bioequivalence study of Terifunomide 14 mg tablets of Zahravi pharmaceutical Co. (@Trigio) versus Aubagio® (Sanofi Genzyme 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 Training 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 Genzyme 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 (C_{max}); 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

Country

Iran (Islamic Republic of)

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Email address

molavif@tbzmed.ac.ir

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 ≤ 90/60 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 Zarafshan & 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 (C_{max})

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 Genzyme 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

Hamed Hamishehkar

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Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahravi pharmaceutical company

Full name of responsible person

Hussein Eslami

Street address

No. 23, Entrance No. 2, Darupakhsh Factories, Daropakhsh St., Karaj (Lashgari) Special Road, 18th Corner, Tehran

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Email

CEO@zahravipharma.com

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

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Jaber Emami

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Fatima Molavi

Position

PhD Student of pharmaceutics

Latest degree

Medical doctor

Other areas of specialty/work

Pharmaceutics

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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