Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

In vivo fasted-state bioequivalence study of Teriflunomide Tablets manufactured by Sobhan oncology Pharmaceutical Co. compared to innovator product

Protocol summary

Study aim
In vivo fasted-state bioequivalence study of Terflunomide 14 mg tablet

Design
The clinical trial has control and test groups with crossover, randomized design, without blinding on twenty-four healthy volunteers. To randomly assign participants in two groups, the lottery method will be used.

Settings and conduct
After oral administration of 14 mg tablet to qualified volunteer, the blood samples will be collected up to 72 hours. Each volunteer will receive a single dose of drug in two periods. The concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector. The study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences. There is no blinding in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: General Health in terms of Liver, Heart and Kidney, Age of 18-55 years old. Exclusion criteria: Smoking, Pregnancy, Alcohol and drug addiction, History of drug allergy.

Intervention groups
Intervention group will receive a single oral dose of test drug product (Teriflunomide 14 mg tablet manufactured by Sobhan Oncology, Iran) and Control group will receive a single dose of reference drug product (Teriflunomide 14 mg tablet manufactured By sanofi Co.). Washout period will be Four weeks. Considering the cross-over nature of the study, in the second week, intervention group will receive the Teriflunomide reference tablet and Control group will receive Teriflunomide tablet of Sobhan Oncology Co. then the blood sampling process will be repeated.

Main outcome variables
Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220211053992N66**
Registration date: **2026-04-27, 1405/02/07**
Registration timing: **prospective**

Last update: **2026-04-27, 1405/02/07**
Update count: **0**

Registration date
2026-04-27, 1405/02/07

Registrant information

Name
Hadi Valizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 8801

Email address
valizadehh@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-21, 1405/02/31

Expected recruitment end date
2027-01-20, 1405/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
In vivo fasted-state bioequivalence study of Teriflunomide Tablets manufactured by Sobhan oncology Pharmaceutical Co. compared to innovator product

Public title
Bioequivalence study of Teriflunomide tablet

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
General Health (in terms of Liver, Heart and Kidney) Age (18-55 years)

Exclusion criteria:
Smoking History of drug allergy Pregnancy Alcohol and drug addiction

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.

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
Ethics Committee of Tabriz University of Medical Sciences

Street address
No.2 Central Building 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Approval date
2026-04-13, 1405/01/24

Ethics committee reference number
IR.TBZMED.REC.1405.037

Health conditions studied

1

Description of health condition studied
In the present study, the products will be administered to healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of drug

Timepoint
Before drug administration and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 12, 24, 48 and 72 hours after drug administration

Method of measurement
HPLC (High performance liquid chromatography)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group will receive a single oral dose of test product (Teriflunomide 14 mg tablet manufactured by Sobhan Oncology, Iran) in fasted state. Samples will be collected for 72 hours. Washout period will be Four weeks. In the second week this group will receive Teriflunomide 14 mg tablet manufactured in canada and the blood sampling process will be repeated.

Category
Treatment - Drugs

2

Description
Control group: Control group will receive a single oral dose of reference product (Teriflunomide 14 mg tablet manufactured in Canada) in fasted state. Samples will be collected for 72 hours. Washout period will be Four

weeks. In the second week this group will receive Teriflunomide 14 mg tablet manufactured by Sobhan Oncology Co. and the blood sampling process will be repeated.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Pharmacy, Tabriz University of Medical Sciences

Full name of responsible person
Hadi Valizadeh

Street address
Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori st., Golgasht st.

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+98 41 3334 4798

Email
valizadehh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sobhan Oncology Co.

Full name of responsible person
Hamed Mohammadpour

Street address
Third Street, Sanat Boulevard 2, Industrial City

City
Rasht

Province
Guilan

Postal code
4337188657

Phone
+98 13 8822 4131

Email
info@sobhanoncology.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Sobhan Oncology Co.

Proportion provided by this source
100

Public or private sector
Public

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
Hadi Valizadeh

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, Attar Neishaboori st., Golgasht st.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

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Position
Professor

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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable