Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Bioequivalence study of eltrombopag 50 mg tablet manufactured by Nanodaru Co versus originator brand (Revolade 50 mg) manufactured by Novartis Co. in fasting condition in healthy volunteers

Protocol summary

Study aim
Bioequivalence study of Eltrombopag 50 mg tablet manufactured by Nanodaru Co. versus originator brand (Revolade® 50 mg) manufactured by Novartis Co in fasting condition in healthy volunteers.

Design
Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization

Settings and conduct
The study is a single-blinded (Volunteers), cross-over and fasting, and on two series of healthy volunteers. The study will be done in two periods (72h). The interval between these two periods is 2 weeks. In the first round of the study, the candidates were divided into two groups the first group received a test tablet and the second group received a brand tablet. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. Sampling is performed in Radin laboratory in Tabriz.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: General Health (Liver, Heart, and Kidney), Body Mass Index (18-28), Informed consent, Age (18-55 years old) Exclusion criteria: Smoking, History of cardiovascular disease, History of liver and kidney disease, Alcohol and drug addiction, History of allergy to Eltrombopag

Intervention groups
Intervention group 1: Revolade 50mg tablet manufactured by Novartis as a reference Intervention group 2: Eltrombopag 50 mg manufactured by Nanodaru as a test

Main outcome variables
Maximum drug concentration, Time to reach maximum drug concentration

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200105046010N109**
Registration date: **2024-06-29, 1403/04/09**
Registration timing: **prospective**

Last update: **2024-06-29, 1403/04/09**
Update count: **0**

Registration date
2024-06-29, 1403/04/09

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
2024-07-20, 1403/04/30

Expected recruitment end date
2025-03-20, 1403/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence study of eltrombopag 50 mg tablet manufactured by Nanodaru Co versus originator brand (Revolade 50 mg) manufactured by Novartis Co. in fasting condition in healthy volunteers

Public title
Bioequivalence study of eltrombopag 50 mg tablet
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) Informed consent Age (18-55 years old)
Exclusion criteria:
Smoking History of cardiovascular disease History of liver and kidney disease Alcoholism and Narcoticism History of allergy to eltrombopag
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **32**
Blood sample
Randomization (investigator's opinion)
Randomized
Randomization description
People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball poured into a container and mixed. The balls are then removed randomly from the container. The first 12 no.s are considered as (first sequence: test medicine) and the second 12 no.s are considered as (second sequence: originator brand recipient). The volunteers don't have any information about taking the test drug or brand drug
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blinded clinical trial (volunteers). Test and Originator brand's tablets 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
Tabriz University of Medical Sciences ethics committe
Street address
Research and technology deputy,3rd floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2024-06-10, 1403/03/21
Ethics committee reference number
IR.TBZMED.REC.1403.201

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers and drug concentration in plasma is determined.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration
Timepoint
0, 1, 12, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24, 48, 72 h after drug administration
Method of measurement
Liquid Chromatography Mass-Mass

Secondary outcomes

1

Description
Time to reach maximum plasma concentration
Timepoint
After intervention
Method of measurement
Time to reach the maximum drug concentration in plasma is recorded.

2

Description
Extent of absorption
Timepoint
After intervention
Method of measurement
Calculation of area under curve of concentration -time

Intervention groups

1

Description
Intervention group: single dose, one oral tablet Revolade 50 mg manufactured by Novartis Co. as a reference product. after washout period, the volunteers received Eltrombopag 50 mg tablet manufactured by Nanodaru Co..
Category
Treatment - Drugs

2

Description
Intervention group: Single dose, one oral Eltrombopag 50 mg tablet manufactured by Nanodaru Co. as test product. after washout period, the volunteers received Revolade 50 mg manufactured by Novartis Co.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Radin laboratory
Full name of responsible person
Javad Shokri
Street address
No.22, first floor, Moalem st., Abureihan St
City
Tabriz
Province
East Azarbaijan
Postal code
5154995671
Phone
+98 914 313 5843
Fax
Email
shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nanodaru Company
Full name of responsible person
Navid Gudarzi
Street address
No. 18, between Sarsabz st and Eta'ati st, Marzdaran blvd
City
Tehran
Province
Tehran
Postal code
1464736141
Phone
+98 21 5810 7000
Email
info@nanodaru.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nanodaru 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
Javad Shokri
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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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 data are as secure between researchers 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
No - There is not a plan to make this available