Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

In vivo Bioequivalence study of Ticagrelor 90 mg Tablet manufactured by Sobhan Daroo Co. on 24 volunteers compared with reference product

Protocol summary

Study aim
In vivo Bioequivalence study of Tcagrelor 90 mg Tablet
Design
Twenty four healthy male volunteer will enter the study based on random numbers table as two groups of twelve people. Each volunteer will receive a single dose of drug in two periods. In one period the test formulation and in another period the reference formulation (without knowing the formulation identity in each period). Therefore each volunteer will be his own "Control".
Settings and conduct
After administration of one 90 mg tablet to volunteer, the blood samples will be taken in predetermined time intervals up to 48 hours. The samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation. In this study the volunteer would not be aware of the formulation identity in each period.
Participants/Inclusion and exclusion criteria
Healthy Male Volunteers without any Heart, Liver and Kidney Diseases
Intervention groups
Each volunteer will receive a single dose of drug in two periods. In one period the test formulation and in another period the reference formulation. Therefore each volunteer will be his own "Control".
Main outcome variables
Being/not being bioequivalence between two products based on FDA guidelines

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210519051345N1**
Registration date: **2021-06-14, 1400/03/24**
Registration timing: **prospective**
Last update: **2021-06-14, 1400/03/24**
Update count: **0**
Registration date
2021-06-14, 1400/03/24

Registrant information
Name
Parvin Zakeri-Milani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3334 8801
Email address
pzakeri@tbzmed.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-08-21, 1400/05/30
Expected recruitment end date
2021-09-21, 1400/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
In vivo Bioequivalence study of Ticagrelor 90 mg Tablet manufactured by Sobhan Daroo Co. on 24 volunteers compared with reference product

Public title
In vivo Bioequivalence study of Ticagrelor Tablet
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:

Being Healthy without any Heart, liver and kidney diseases

Exclusion criteria:

Having any kind of illnesses

Age

From **25 years** old to **55 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the Table of Random Numbers

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, Volunteers participating will be blinded to the type of product they are taking in each period (test or reference product). This means that the product will be given to the volunteers for administration outside the original packaging

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Biomedical Research Committe, Tabriz University of Medical Sciences

Street address

Golgasht st. Attar Neishabouri st. Faculty of Pharmacy, Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Approval date

2021-05-17, 1400/02/27

Ethics committee reference number

IR.TBZMED.REC.1400.164

Health conditions studied

1

Description of health condition studied

In the present study, no diseases will be examined and products will be administered by healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma Drug Concentration

Timepoint

0.5-48 hours in predetermined time intervals

Method of measurement

HPLC

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Healthy volunteers

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Pharmacy Tabriz University of Medical Sciences

Full name of responsible person

Parvin Zakeri-Milani

Street address

Golgasht st. Attar Neishaboori st. Faculty of Pharmacy, Tabriz University of Medicl Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Email

pzakeri@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mohammad Samiei

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

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3335 7310

Email
Samiei.moh@gmail.com

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Sobhan Daroo 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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parvin Zakeri-Milani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Email
pzakeri@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parvin Zakeri-Milani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Gogasht st., Attar Neishaboori st., Faculy of Pharmacy, Tabriz University of Medical Siences

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
009841133348801

Email
pzakeri@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parvin Zakeri-Milani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Email
pzakeri@tbzmed.ac.ir

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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available