

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence study of Dasatinib 100mg tablet manufactured by Actero pharma (Dotixa) versus Sprycel 100 mg in healthy volunteers in the fasted condition

Protocol summary

Study aim

Determining the bioequivalence Study of Dasatinib 100mg tablet manufactured by Actero company (Dotixa) versus originator brand (Sprycel) manufactured by Bristol-mayer company

Design

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

Settings and conduct

The study is a single-blinded, cross-over, and fasting condition, on two series of healthy volunteers. The study will be done in two periods (24h). The interval between these two periods is one week. The candidates were divided into two groups in the first round of the study. the first group receives a test tablet and the second group receives 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. These steps are 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 dasatinib

Intervention groups

Intervention group 1: Sprycel 100mg tablet as a reference Intervention group 2: Dotixa 100mg 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: **IRCT20200105046010N81**

Registration date: **2023-09-25, 1402/07/03**

Registration timing: **prospective**

Last update: **2023-09-25, 1402/07/03**

Update count: **0**

Registration date

2023-09-25, 1402/07/03

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

2023-10-07, 1402/07/15

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Dasatinib 100mg tablet manufactured by Actero pharma (Dotixa) versus Sprycel 100 mg in healthy volunteers in the fasted condition

Public title

Bioequivalence study of Dasatinib 100 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 Alcohol and drug addiction History of allergy to dasatinib

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**

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: Actero's 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). Actero's Dasatinib and Originator brand 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

Research Ethics Committees of Tabriz University of Medical Sciences

Street address

Research and Technology Vice-Chancellor, 3rd floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2023-09-04, 1402/06/13

Ethics committee reference number

IR.TBZMED.REC.1402.451

Health conditions studied

1

Description of health condition studied

This study is performed on healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

Immediately before and 0.25, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12 and 24h 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 drug 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 100mg(Sprycel) manufactured by Bristol-mayer, as a reference product
Category
Treatment - Drugs
- 2**
Description
Intervention group: Single dose, one oral Dotixa 100 mg tablet manufactured by Actero company as a test product
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, Azadi alley, Moalem st., Abureihan St
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- Province**
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1446863914
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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
Actero Pharma 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
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Other areas of specialty/work
Medical Pharmacy
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- Sponsors / Funding sources**
- 1**
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Name of organization / entity
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Other areas of specialty/work

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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

Person responsible for updating data**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