

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of the Amiodarone 200-mg Tablets manufactured by Behestan Pharmaceutical Company

Protocol summary

Study aim

Examining the equivalency of domestically produced tablet formulations with brand samples

Design

Cross-over unblinded randomization

Settings and conduct

The number of 24 healthy volunteers in the age range of 18-60 years and the weight range of $18 < \text{BMI} < 30$, male, who are randomly and voluntarily selected through public notification. 1 tablet is taken fasting and blood is taken at 15 time points. A week later, the process is repeated for the external medicine.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - The weight range of participating candidates should be between 60-100 kg. - All candidates must be non-smokers. - They must be healthy in terms of liver, kidney, respiratory, cardiac, nervous and mental status and other general health characteristics that will be evaluated. - Volunteers who have agreed to the informed consent form. Exit criteria: - History of sensitivity or idiosyncrasy to amiodarone or any of the inactive components of the formulation. - Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg. - Taking any medication within 2 weeks before receiving the medication.

Intervention groups

After taking a pill for internal production, 3 milliliters of blood will be collected from the volunteer in 15 time intervals for 72 hours. A week later, the process is repeated for a brand sample tablet. The drug concentration is measured in plasma.

Main outcome variables

Studying the Drug pharmacokinetic parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130313012810N7**

Registration date: **2023-01-09, 1401/10/19**

Registration timing: **retrospective**

Last update: **2023-01-09, 1401/10/19**

Update count: **0**

Registration date

2023-01-09, 1401/10/19

Registrant information

Name

Hamed Hamishehkar

Name of organization / entity

Drug Applied Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 3311

Email address

hamishehkar.hamed@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-26, 1401/10/05

Expected recruitment end date

2023-01-01, 1401/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of the Amiodarone 200-mg Tablets manufactured by Behestan Pharmaceutical Company

Public title

Comparative bioequivalence study of the Amiodarone
200-mg Tablets manufactured by Behestan
Pharmaceutical Company

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

The weight range of participating candidates must be between 60-100 kg All candidates must be non-smokers
The candidates must be healthy in terms of physical examination, ECG and the following laboratory tests: hemoglobin, hematocrit, red and white blood count, MCV (mean body mass), MCH (mean body hemoglobin), routine urinalysis, total cholesterol, triglycerides, total proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), amino aspartate transferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose
Volunteers who agreed to the informed consent form

Exclusion criteria:

History of sensitivity or idiosyncrasy to amiodarone or any of the inactive components of the formulation.
Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg. Taking any medication within 2 weeks before receiving the medication.

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

N/A

Randomization description**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

خیابان دانشگاه، مرکز تحقیقات کاربردی دارویی

City

Tbriz

Province

East Azarbaijan

Postal code

51656-65811

Approval date

2022-12-19, 1401/09/28

Ethics committee reference number

IR.TBZMED.REC.1401.846

Health conditions studied**1****Description of health condition studied**

bioequivalence study

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Plasma concentration of the drug

Timepoint

15 sampling time till 72 h

Method of measurement

Liquid Chromatography with tandem mass spectrometry
(LC-MS-MS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: This study examines the bioequivalence of amiodarone tablets produced by a domestic company with a foreign brand sample. We have only one intervention group and there is no control group. The intervention group, which includes healthy, fasting male volunteers, will receive a single dose, a 200 mg tablet manufactured by the pharmaceutical company Behestan and Sanofi brand, in two 72-hour periods with an interval of one month, on the first day of the study. In 14 different time periods up to 72 hours after taking the medicine, blood samples will be taken from the volunteers in the amount of 3 ml each time, that is, a total of 42 ml within 72 hours. The training that will be given to the volunteers includes avoiding the consumption of drinks containing alcohol and xanthine and other interfering drugs in the prescription drug from 48 hours before the start of the study until the end of the study

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug Applied Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Street address

Daneshgah St. Drug Applied Research Center

City

Tabriz

Province

East Azarbaijan

Postal code

51656-65811

Phone

+98 41 3336 3311

Email

hamishehkar.hamed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Behestan Daru Co

Full name of responsible person

Mehdi Oruji

Street address

Behestan Building, No. 10, Pardis St., Mollasadra St., Vanak Square

City

Tehran

Province

Tehran

Postal code

1991915613

Phone

+98 21 8877 4200

Email

info@behestandarou.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Behestan Daru Co

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

Medical Pharmacy

Street address

Drug Applied Research Center-Tabriz University of Medical Science

City

Tabriz

Province

East Azarbaijan

Postal code

51656-65811

Phone

+98 41 3336 3181

Email

hamishehkar.hamed@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Position

Professor

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Phone

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Fax

+98 41 1336 3311

Email

hamishehkar.hamed@gmail.com

Person responsible for updating data

Contact

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Tabriz University of Medical Sciences

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Street address

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City

Tabriz

Province

East Azarbaijan

Postal code

51656-65811

Phone

+98 41 3336 3181

Fax

+98 41 3336 3311

Email

hamishehkar.hamed@gmail.com

Web page address

<http://darc.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

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