Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparative bioequivalence study of the Nicorandil 20-mg tablets manufactured by Modava Pharmaceoutical 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 < 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
The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form

Intervention groups
After taking a pill for internal production, 3 milliliters of blood will be collected from the volunteer in 15 time intervals for 48 hours. A week later, the process is repeated for a brand sample pill. 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: **IRCT20130313012810N6**
Registration date: **2022-12-25, 1401/10/04**
Registration timing: **prospective**

Last update: **2022-12-25, 1401/10/04**
Update count: **0**

Registration date
2022-12-25, 1401/10/04

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
2023-01-10, 1401/10/20

Expected recruitment end date
2023-01-18, 1401/10/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of the Nicorandil 20-mg tablets manufactured by Modava Pharmaceoutical

company

Public title
Comparative bioequivalence study of the Nicorandil 20-mg tablets manufactured by Modava Pharmaceoutical company

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form

Exclusion criteria:
History of allergic or adverse reaction to nicorandil or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg. smokers People who have participated in other clinical studies or bioequivalence studies within 3 months before the first day of use Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s)

Age
From **18 years** old to **60 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
Daneshghah St. Drug Applied Research Center

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Approval date
2022-12-19, 1401/09/28

Ethics committee reference number
IR.TBZMED.REC.1401.850

Health conditions studied

1

Description of health condition studied
-

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of the drug

Timepoint
13 sampling time till 8 h

Method of measurement
LCMSMS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: This study examines the bioequivalence of nicorandil 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 20 mg tablet manufactured by the pharmaceutical company Modava and Merck brand, in two 8-hour periods with an interval of one week, on the day of the study. And in 13 different time periods up to 8 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 39 ml within 8 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

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hamishehkar.hamed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Modava Pharmaceutical Company

Full name of responsible person

Asghar Heydari

Street address

5th floor, Shafayab Building, No. 275, Beheshti St.

City

Tehran

Province

East Azarbaijan

Postal code

1514617714

Phone

+98 21 8817 5119

Email

info@modavaco.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Modava Pharmaceutical 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

Drug Applied Research Center, 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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Hamed Hamishehkar

Position

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Person responsible for updating data

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Web page address

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