Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A randomized, open label, single dose, crossover, bioequivalence study of Flecainide 100mg tablet of Vana Darou Gostar Pharm Co., IRAN in comparison of Tambocor 100mg tablet of Meda in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

A randomized, open label, single dose, crossover, bioequivalence study of test product (Flecainide 100mg tablet of Vana Darou Gostar Pharm Co., IRAN) in comparison of reference product (Tambocor 100mg tablet of Meda) in 24 healthy adult subjects under fasting condition

Design

A randomized, open label, single dose, crossover, bioequivalence study in 24 healthy subjects under fasting condition

Settings and conduct

This study is carried out in Core Research Center of Zahedan University of Medical Sciences located in Imam Ali Hospital in Zahedan. There is a separate space for sampling and forecasting emergency situations in order to accommodate and rest the volunteers. This crossover and open label study was performed on 24 healthy volunteers. The volunteers' health is verified by the project physician prior to entry into the study, and the volunteers' status is regularly monitored by the project physician on the day of drug administration. This study will be covered by insurance in order to compensate for any adverse effects.

Participants/Inclusion and exclusion criteria

Main Inclusion criteria: Healthy subjects aged between 18 -50 years old and weighted between 50 – 100 kg\\ Main exclusion criteria: History of GI surgery; Donation a unit of blood or participated in another clinical trial within the last two months; History of drug or alcohol abuse; Used any medication within 7- 14 days before the first treatment;

Intervention groups

Intervention: Flecainide 100mg tablet, produced by Vana Darou Gostar Pharm Co (IRAN), single dose. Control: Single dose of one Tambocor 100mg tablet of Meda

Main outcome variables

Plasma concentration of Flecainide at 0 (before dosing), 1.0, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 24.0 & 48.0 hr. after dosing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N23**
Registration date: **2021-07-11, 1400/04/20**
Registration timing: **prospective**

Last update: **2021-07-11, 1400/04/20**
Update count: **0**

Registration date

2021-07-11, 1400/04/20

Registrant information

Name

Ladan Tayebi

Name of organization / entity

Pars Biopharmacy Research Co.

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 6061

Email address

l.tayebi@parsbiopharmacy.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date
2022-03-20, 1400/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized, open label, single dose, crossover, bioequivalence study of Flecainide 100mg tablet of Vana Darou Gostar Pharm Co., IRAN in comparison of Tambocor 100mg tablet of Meda in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Flecainide 100mg tablet of Vana Darou Gostar Pharm Co., IRAN
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
- Aged between 18 - 50 years - Body weight between 50 – 100 kg - Having good health on the basis of medical history and physical & clinical examination - Understand the procedures and give written informed consent
Exclusion criteria:
Subject had undergone surgery of the gastro-intestinal tract Subject had donated a unit of blood or participated in another clinical trial, within the last two months before the first treatment. Subject had a history of drug or alcohol abuse. Subject who smokes more than 10 cigarettes per day. Subject had used any prescription medication within 14 days, or any non-prescription medication within 7 days, before the first treatment.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **48**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each volunteer, 2 times take medicine in the study. One-time test product and the other time reference product with at least one week wash-out period.
Randomization (investigator's opinion)
Randomized
Randomization description
Using Excel software, each subject will be randomly assigned to one of the two sequence AB or BA in a balanced manner.
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 Zahedan University of medical Sciences
Street address
Zahedan University of Medical Sciences, Dr. Hessabi square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2021-05-26, 1400/03/05
Ethics committee reference number
IR.ZAUMS.REC.1400.083

Health conditions studied

1

Description of health condition studied
Cardiac arrhythmia
ICD-10 code
I49.9
ICD-10 code description
Cardiac arrhythmia, unspecified

Primary outcomes

1

Description
Plasma concentration of Flecainide
Timepoint
0 (before dosing), 1.0, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 24.0 & 48.0 hr. after dosing
Method of measurement
Using High Performance Liquid Chromatography (HPLC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Flecainide 100mg tablet, produced by Vana Darou Gostar Pharm Co (IRAN), single dose.

Category

N/A

2

Description

Control group: Tambocor, one 100 mg tablet, produced by Meda company, single dose.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Core Research Lab. of Zahedan University of Medical Sciences

Full name of responsible person

Ghasemi Marieh

Street address

Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5664

Fax

+98 54 3329 5665

Email

crl@zaums.ac.ir

Web page address

http://crl.zaums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vana Darou Gostar

Full name of responsible person

Heydari Maryam

Street address

2nd floor, No. 29, Tavanir St. (Shahid Abbaspour)

City

Tehran

Province

Tehran

Postal code

۱۴۳۵۶۴۳۳۱۴

Phone

+98 21 8887 1521

Fax

+98 21 8887 1508

Email

info@vdgco.ir

Web page address

https://vanadarou.com/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vana Darou Gostar

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Pars Biopharmacy Research Co.

Full name of responsible person

Ladan Tayebi

Position

Managing Director

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

1st floor, Saeidi Dd end, Felestin Ave.

City

Tehran

Province

Tehran

Postal code

1416673971

Phone

+98 21 8895 6061

Fax

+98 21 8896 9958

Email

l.tayebi@parsbiopharmacy.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Pars Biopharmacy Research Co.

Full name of responsible person

Ladan Tayebi

Position

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Person responsible for updating data

Contact

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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

Not applicable

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