

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

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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.

AgeFrom **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

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

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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)

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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

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Full name of responsible person

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Position

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Latest degree

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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