Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Effectiveness of Dorocontin and Sustak Drugs on Treatment of Ischemic Heart Disease

Protocol summary

Summary

Due to the economic aspects, in this study the efficacy and safety of oral sustained release drug made inside country (Dorocontin) is compared with an importing drug (Sustak). It can halt export of millions of dollars from our country. This study was initiated at April 2011. It was carried out on 140 cases in Bqyiatallah hospital as a random, double blind, uni-central, parallel, without control. In this study, Inclusion criteria include Having clinical signs of IHD; on the other hand Exclusion criteria involves any Background diseases, Having signs of unstable angina, and any Simultaneous drug conflicts. Some parameters such as joints pain, AlkP, LDH, sGOT, Tachypnea, Dyspnoeic, Headache, Organ edema, Vomiting, Nausea, BUN, Serum Cratinine, sGPT, Heart Functional Activity, Resistance against Physical Activities, and Hypertension were used to evaluate clinical conditions of cases.

General information

Acronym

Effectiveness of Dorocontin on IHD

IRCT registration information

IRCT registration number: **IRCT2014051516563N2**
Registration date: **2014-08-11, 1393/05/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-08-11, 1393/05/20

Registrant information

Name

Hojat Borna

Name of organization / entity

Baqiyatallah University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8248 2503

Email address

h_borna@hotmail.com

Recruitment status

Recruitment complete

Funding source

Dorsa Daroo Company

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effectiveness of Dorocontin and Sustak Drugs on Treatment of Ischemic Heart Disease

Public title

Effectiveness of Dorocontin and Sustak Drugs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: Being higher than 40 years old Having clinical signs of IHD (stable angina) like a chest pain which increases during activities and decreases during rest and usage of drug Exclusion: Having background diseases (diabetes, kidney failure, hyperpressure, & ...) Having clinical and lab signs of unstable angina or anfractuous (ECG changes along with increased levels of cardiac enzymes) Simultaneous drug conflicts and bronchodilators such as calcium channel blockers, sildenafil

Age
From **40 years** old to **100 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Baqiyatallah University of Medical Sciences
Street address
Sheikh-e-Bahaiee St., Mollasadra St., Vanak Sq., Tehran, Iran
City
Tehran
Postal code
Approval date
2011-03-03, 1389/12/12
Ethics committee reference number
441

Health conditions studied

1

Description of health condition studied
Chronic Ischaemic Heart Disease
ICD-10 code
I25.9
ICD-10 code description
Chronic ischaemic heart disease

2

Description of health condition studied
Silent Myocardial Ischaemia
ICD-10 code
I25.6
ICD-10 code description
Silent myocardial ischaemia

3

Description of health condition studied
Acute Ischaemic Heart Disease
ICD-10 code
I24.9
ICD-10 code description
Acute ischaemic heart disease

4

Description of health condition studied
Acute Ischaemic Heart Disease, Unspecified
ICD-10 code
I24.8
ICD-10 code description
Acute ischaemic heart disease, unspecified

5

Description of health condition studied
Acute Ischaemic Heart Disease, Unspecified
ICD-10 code
I25.8
ICD-10 code description
Acute ischaemic heart disease, unspecified

6

Description of health condition studied
Family History of Ischaemic Heart Disease and Other Diseases of the Circulatory System
ICD-10 code
Z82.4
ICD-10 code description
Family history of ischaemic heart disease and other diseases of the circulatory system

Primary outcomes

1

Description
Paintful joints
Timepoint
after and before treatment
Method of measurement
qualitative tests and quality of life tests

2

Description
AlkP
Timepoint
after and before treatment
Method of measurement
serologic tests

3

Description
LDH
Timepoint
after and before treatment
Method of measurement
serologic tests

4

Description
sGOT
Timepoint
after and before treatment
Method of measurement
serologic tests

5

Description
Tachypnea
Timepoint
after and before treatment
Method of measurement
qualitative tests and quality of life tests

6

Description
Dyspnoeic
Timepoint
after and before treatment
Method of measurement
qualitative tests and quality of life tests

7

Description
Headache
Timepoint
after and before treatment
Method of measurement
qualitative tests and quality of life tests

8

Description
Organ edema
Timepoint
after and before treatment
Method of measurement
qualitative tests and quality of life tests

9

Description
Vomiting
Timepoint
after and before treatment
Method of measurement
qualitative tests and quality of life tests

10

Description
Nausea
Timepoint
after and before treatment
Method of measurement
qualitative tests and quality of life tests

11

Description
BUN
Timepoint
after and before treatment
Method of measurement
serologic tests

12

Description
Serum Cratinine
Timepoint
after and before treatment
Method of measurement
Biochemistry Tests

13

Description
sGPT
Timepoint
after and before treatment
Method of measurement
Biochemistry Tests

14

Description
Heart Functional Activity and Resistance Against Physical Activities
Timepoint
after and before treatment
Method of measurement
Exercise Test

15

Description
Hypertension
Timepoint
after and before treatment
Method of measurement
Blood Pressure Measurement Tests

Secondary outcomes

1

Description
Possible Drug Interventions
Timepoint
after treatment

Method of measurement
Quanlitative tests

Intervention groups

1

Description
4.6 mg nitrocantin tablets (sustained nitrogycerin) with 3 doses per day for 2 months
Category
Treatment - Drugs

2

Description
4.6 mg sustak tablets (sustained nitrogycerin) with 3 doses per day for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah University of Medical Sciences
Full name of responsible person
Prof. Younes Panahi
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dorsa Daroo Pharmaceutical Company
Full name of responsible person
Prof. Younes Panahi
Street address
Shekh-e-Bahaiee St., Mollasadra St., Vanak Sq.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dorsa Daroo Pharmaceutical Company
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Prof. Younes Panahi
Position
Phd of Clinical Pharmacology/Dean of Chemical Injuries Research Center
Other areas of specialty/work
Street address
Sheikh-e-Bahaiee St., Mollasadra St., Vanak Sq.,
City
Tehran
Postal code
Phone
+98 21 8248 2503
Fax
Email
yunespanahi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences, tehran, iran
Full name of responsible person
Prof. Younes Panahi
Position
Phd of Clinical Pharmacology
Other areas of specialty/work
Street address
Sheikh-e-bahaiee St., Mollasadra St., Vanak Sq.,
City
Tehran
Postal code
Phone
+98 21 8248 2503
Fax
Email
yunespanahi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Prof. Younes Panahi
Position
Phd of Clinical Pharmacology
Other areas of specialty/work
Street address

Shaikh-e-bahaiee St.,Mollasadra St., Vanak Sq.,

City

Tehran

Postal code

Phone

+98 21 8248 2503

Fax

Email

yunespanahi@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty