

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 Bqiyatallah 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 anfractuou (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

Painful 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 nitroglycerin) with 3 doses per day for 2 months

Category

Treatment - Drugs

2**Description**

4.6 mg sustak tablets (sustained nitroglycerin) 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