

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Double Blind Randomized Clinical Trial for Evaluation of Sildenafil and placebo effects on improvement of clinical and paraclinical measures on patients with severe Systolic Heart Failure

Protocol summary

Summary

Patients with heart failure and LVEF less than 35% and NYHA FC II and more will be selected . Primary data including echocardiographic measures and laboratory data including BS, Uric acid , Cr, BUN , CRP , CBC , Total Chl , TG , LDL , HDL , Bil (T and D) , AST , ALT and 6-minute walk test and complete history taking will be taken . Drug history of patients will be scrutinized and will be adjusted so that every patient taking at least the standard 4-drug heart failure regimen at least for 2 weeks . According to inclusion and exclusion criteria patients will be entered to the study and randomly assigned into two groups . Drug and placebo will be started with 25mg single dose at bedtime and gradually increasing upto maximum dosage of 50mg twice daily. Patients will be visited at 2 , 4 , 8 and 12 weeks and monitored for vital signs , probable adverse drug reactions and all the clinical and paraclinical data will be examined again at the end of the survey and collected data will be analyzed . In addition if during the follow up visits , any adverse reaction or intolerance were seen , the patient will quit from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101045544N1**
Registration date: **2011-06-06, 1390/03/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-06, 1390/03/16

Registrant information

Name

Hossein Navid

Name of organization / entity

Shaheed Rajaei Heart Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 0946

Email address

dr_hona@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research shahid Rajaei research center

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double Blind Randomized Clinical Trial for Evaluation of Sildenafil and placebo effects on improvement of clinical and paraclinical measures on patients with severe Systolic Heart Failure

Public title

Evaluation of Sildenafil and placebo effects on improvement of clinical and paraclinical measures on patients with severe heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Adult with at least class II CHF ; Able to give Informed consent
Exclusion Criteria : Unable to give informed consent ; Currently taking nitrates ; Comorbid condition(s) that could limit walking ; resting SBP<90mmHg

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Tehran University of medical science

Street address

Pardis Hemmat branch

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

4258

Health conditions studied

1

Description of health condition studied

Ischemic cardiomyopathy

ICD-10 code

I25.5

ICD-10 code description

Ischaemic cardiomyopathy

2

Description of health condition studied

Dilated cardiomyopathy

ICD-10 code

I42.0

ICD-10 code description

Congestive cardiomyopathy

Primary outcomes

1

Description

exertional dyspnea

Timepoint

before trial and then every 2 weeks for one month and monthly thereafter

Method of measurement

NYHA functional class classification

2

Description

6-minute walk test

Timepoint

Before and after trial

Method of measurement

total distance walked

3

Description

Quality of life (QoL)

Timepoint

Before and at the end

Method of measurement

MacNew HRQL Questionnaire- Farsi version

4

Description

Left ventricular ejection fraction(EF)

Timepoint

before and at the end

Method of measurement

Echocardiography with Vivid3 for measuring LVEF by 2D and simpson method.

Secondary outcomes

1

Description

mortality

Timepoint

every 2 week twice then monthly for 3 month.

Method of measurement

Mortality

2

Description

Headache
Timepoint
every 2 week twice then monthly for 3 month.
Method of measurement
Questionnaire

3

Description
Hypotension
Timepoint
every 2 week twice then monthly for 3 month
Method of measurement
BP measurement with mercury sphygmomanometer

4

Description
Priapism
Timepoint
every 2 week twice then monthly for 3 month
Method of measurement
Questionnaire

Intervention groups

1

Description
According to the study design (Randomized and double blinded) ; eligible patients are given by chance drug or placebo with dose of 25mg at bedtime for 1 week and up titrated to 25mg twice daily for the next week . After 2week visit according to the patient`s condition dose will be increased up to 50mg twice daily .
Category
Treatment - Drugs

2

Description
According to the study design (Randomized and double blinded) ; eligible patients are given by chance drug or placebo with dose of 25mg at bedtime for 1 week and up titrated to 25mg twice daily for the next week . After 2week visit according to the patient`s condition dose will be increased up to 50mg twice daily .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaee Heart center
Full name of responsible person
Hossein Navid
Street address
Valiasr (AJ) st , Niayesh Highway
City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research shahid Rajaee research center
Full name of responsible person
Majid Hghjoo M.D
Street address
Shahid Rajaee Hospital , Valiasr st , Niayesh Highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research shahid Rajaee research center
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
Shahid Rjaee Heart Center
Full name of responsible person
Hossein Navid M.D
Position
Resident of cardiology
Other areas of specialty/work
Street address
Valiasr (AJ) , Niayesh Highway
City
Tehran
Postal code
Phone
+98 21 23921
Fax
Email
dr_hona@yahoo.com
Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Shahid Rajaee Heart Center

Full name of responsible person

Ahmad Amin M.D

Position

Associated Professor

Other areas of specialty/work

Street address

Valiasr (AJ) st , Niayesh Highway

City

Tehran

Postal code

Phone

+98 21 2392 2172

Fax

Email

aamin@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Rajaee Heart Center

Full name of responsible person

Hossein Navid M.D

Position

Resident of cardiology

Other areas of specialty/work

Street address

Valiasr (AJ) , Niayesh Highway

City

Tehran

Postal code

Phone

+98 21 23921

Fax

Email

dr_hona@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