Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 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 Rajaee Heart Hospital
Country
Iran (Islamic Republic of)
Phone
+98 21 2200 0946
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dr_hona@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research shahid Rajaee 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
125.5
ICD-10 code description
Ischaemic cardiomyopathy

2

Description of health condition studied
Dilated cardiomyopathy
ICD-10 code
142.0
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

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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

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Person responsible for updating data

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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