

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Beneficial effects of Testosterone therapy on functional capacity, cardiovascular parameters, and quality of life in patients with Congestive Heart Failure

Protocol summary

Summary

Methods: A total of 50 male patients who suffered from congestive heart failure were recruited in a double-blind, placebo-controlled trial and randomized to receive an intramuscular (gluteal) long-acting androgen injection (1 mL of testosterone enantate 250mg/ml) once every four weeks for 12 weeks or receive intramuscular injections of saline (1 mL of 0.9% wt/vol NaCl) with the same protocol. Measurements to the study including assessment of cardiovascular parameters, quality of life and depression status were performed before intervention and also as endpoint after 12 weeks. Also, the changes in body weight, muscle strength, 6-min walk distance (6MWD), functional capacity as well as hemodynamic indicators were assessed at baseline and also at the end of each month in both groups and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013070113828N1**

Registration date: **2013-10-20, 1392/07/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-20, 1392/07/28

Registrant information

Name

Ahmad Mirdamadi

Name of organization / entity

Islamic Azad university ,Najafabad branch

Country

Iran (Islamic Republic of)

Phone

+98 31 1223 8028

Email address

drsamirdamadi@pmd.iaun.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University, Najafabad Branch

Expected recruitment start date

2013-09-14, 1392/06/23

Expected recruitment end date

2014-03-14, 1392/12/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Beneficial effects of Testosterone therapy on functional capacity, cardiovascular parameters, and quality of life in patients with Congestive Heart Failure

Public title

Evaluation of Testosterone therapy in Heart Failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were: 1 -Male Gender and age 50-80 with 2 - Heart Failure approved by Echocardiography and 6MWT test 3 -Having clinically stable heart condition in the last three months and not hospitalized for heart failure problems 4 - Classes II and III are classified as being in NYHA 5 - Ejection fraction(EF) less than 40 percent 6 - No signs of unstable angina and myocardial infarction in recent months 7 - Absence of severe liver and pulmonary disease 8 -Absence of uncontrolled

hypertension 9 - No erythrocytosis (hematocrit \geq 50%) 10
- No history of breast and prostate cancer and no history
of prostate nodules, 11 - Absence of lower urinary tract
symptoms and severe BPH disease and high levels of
PSA 12 - Consent patients into the study. Exclusion
criteria were: 1 - Cancel patient continued therapy 2 -
Patient not continue more than a month after the
injection, 3 - oversensitivity to drug and important side
effects - 4 patients died during the study.

Age

From **50 years** old to **80 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Isfahan University Of Medical Sciences

Street address

Isfahan University, Azadi Square, Isfahan

City

Isfahan

Postal code

Approval date

2013-09-12, 1392/06/21

Ethics committee reference number

12/182/م/4/پ

Health conditions studied

1

Description of health condition studied

Congestive Heart Failure

ICD-10 code

I50

ICD-10 code description

I50.0

Primary outcomes

1

Description

Assessment of Cardiovascular parameter like Ejection
Fraction/Diastolic function and Left Ventricular
Dimensions at the end of Systole and Diastole

Timepoint

Before intervention and also as endpoint after 12 weeks

Method of measurement

Echocardiography

2

Description

Quality Of Life

Timepoint

Before intervention and also at endpoint after 12 weeks

Method of measurement

Quality Of Life Questionnaire

3

Description

Depression status

Timepoint

Before intervention and also at endpoint after 12 weeks

Method of measurement

Beck Questionnaire

4

Description

Changes in body weight

Timepoint

Baseline and also at the end of each month

Method of measurement

Weight scale

5

Description

Muscle strength

Timepoint

Baseline and also at the end of each month

Method of measurement

Hand Dynamometer

6

Description

6-Minute Walk Distance (6MWD)

Timepoint

Baseline and also at the end of each month

Method of measurement

Measurement of distance that patients had walked within
6 minute in hospital corridor

Secondary outcomes

1

Description

PSA measure

Timepoint

Before intervention and also as endpoint after 12 weeks

Method of measurement

ELISA Method

Intervention groups

1

Description

Case group:Patients with Heart Failure who undergo intramuscular injection of long acting testosterone(1 mL of testosterone enatated 250mg/ml)each 4 weeks up to 12 weeks.

Category

Treatment - Drugs

2

Description

Placebo group:Patients with heart failure who undergo saline injection(1ml)each 4 weeks each 4 weeks up to 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Hospital

Full name of responsible person

Dr.Mirdamadi

Street address

Sheikhbahaei Street, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Najafabad Branch

Full name of responsible person

Dr.Mirdamadi

Street address

Najafabad, Isfahan

City

Najafabad

Grant name

Grant code / Reference number

Nothing

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University, Najafabad Branch

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University, Najafabad Branch

Full name of responsible person

Dr.Mirdamadi

Position

Cardiologist,Fellowship of Echocardiography/Assistant professor of medical school

Other areas of specialty/work

Street address

Sheikhbahaei Street, Isfahan Hospital,

City

Isfahan

Postal code

Phone

+98 31 1233 0015

Fax

+98 31 1223 8028

Email

drsamirdamadi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University, Najafabad Branch

Full name of responsible person

Dr.Mirdamadi

Position

Cardiologist,Fellowship of Echocardiography/Assistant professor of medical school

Other areas of specialty/work

Street address

Sheikhbahaei Street, Isfahan Hospital,

City

Isfahan

Postal code

Phone

+98 31 1233 0015

Fax

+98 31 1223 8028

Email

drsamirdamadi@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