

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Investigating the effect of nandrolone on the quality of life in female patients with heart failure

Protocol summary

Registration timing: **prospective**

Study aim

Investigating the effect of nandrolone on the quality of life in female patients with heart failure

Last update: **2023-12-30, 1402/10/09**

Update count: **0**

Design

A single-blinded clinical trial with parallel groups and phase 3 that will be conducted on 90 patients. Patients will be assigned to one of the intervention or placebo groups using the block randomization method using the generated -computer numbers by the Random Allocation software.

Registration date

2023-12-30, 1402/10/09

Registrant information

Name

Mohammadreza Taban

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

taban@tbzmed.ac.ir

Settings and conduct

This study will be conducted on women with heart failure referred to Tabriz Shahid Madani Hospital. The study will be conducted as a single-blind clinical trial. The patient will be blind about her allocation to the intervention or placebo group. The Syringes of drug and placebo will be similar in shape, size and color.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

In this study, women over 50 years old with FCII and FCIII heart failure will be included. Patients with the occurrence of ischemia in the last 6 months of the disease, hormonal disorders, hypertension and OCP use will not be included in the study.

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-04-19, 1403/01/31

Intervention groups

Patients in the intervention group will receive nandrolone decanoate 25 mg intramuscularly once a week for one month, and in the placebo group, 25 mg vials of isotonic solution will be provided by Caspian Pharmaceutical Company.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Quality of Life

Trial completion date

empty

General information

Scientific title

Investigating the effect of nandrolone on the quality of life in female patients with heart failure

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231116060079N1**

Registration date: **2023-12-30, 1402/10/09**

Public title

Investigating the effect of nandrolone on the quality of life

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:
Women with heart failure FCII and FCIII Ejection Fraction less than and equal to 40 Age over 50 years

Exclusion criteria:
Occurrence of ischemia in the last 6 months of the disease Hormonal disorders Consumption of oral contraceptive pill (OCP) Hypertension

Age
From **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly with Block randomization assigned to one of the intervention or placebo groups using computer-generated numbers produced by the Random allocation software. Thus, in this software, the number of groups and the total sample size will be entered, and then the "randomization" will be implemented in the block section. Then, the computer-generated number list will be given to the physician, and the physician will assign patients to groups according to the determined order by the software for entry into one of the groups. Thus, the randomization process will continue until the final sample size is reached.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study will be conducted as a single-blind clinical trial. The patient will be blind about her allocation to the intervention or placebo group. The Syringes of drug and placebo will be similar in shape, size and color.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences., 29 Bahman Blvd., Tabriz., Iran.

City
Tabriz

Province
East Azarbaijan

Postal code
5166616441

Approval date
2023-10-02, 1402/07/10

Ethics committee reference number
IR.TBZMED.REC.1402.489

Health conditions studied

1

Description of health condition studied
Heart failure

ICD-10 code
I50

ICD-10 code description
Heart failure

Primary outcomes

1

Description
Quality of Life

Timepoint
Before and six weeks after the intervention

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Cardiac ejection fraction

Timepoint
Before and six weeks after the intervention

Method of measurement
Eco-cardiography

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive nandrolone decanoate 25 mg intramuscularly once a week for one month that will be provided by Caspian Pharmaceutical Company.

Category
Treatment - Other

2

Description

Control group: Patients in the placebo group will receive 25 mg vials of isotonic solution will be provided by Caspian Pharmaceutical Company.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz Shahid Madani Hospital

Full name of responsible person

Dr.Mahammadreza Taban Sadeghi

Street address

Shahid Madani hospital., Daneshgah Ave.,Tabriz., Iran.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Parviz Shahabi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mahammadreza Taban Sadeghi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Shahid Madani hospital., Daneshgah Ave., Tabriz., Iran.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable