

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2026

Effect of Testosterone on Pulmonary Function in Male with Chronic Obstructive Pulmonary Disease

Protocol summary

Study aim

Determine the Effect of Testosterone on Pulmonary Function and Hormonal Responses in Patients with Chronic Obstructive Pulmonary Disease

Design

clinical trial, Randomised, double blinded with a parallel group design of 80 patients

Settings and conduct

A Double Blind Study Will be Performed on All Patients Under 80 years Old with COPD in Amir Al-Momenin Hospital in Arak. Blind Study Includes Participants, Principal Researcher, Clinical Care and Statistical Analyst. Before Starting the Study, the Patients are Divided in to Three Groups: Mild, Moderate and Severe for BPH, Based on I-PSS Score of the American Urology Society. The Mild Group will be Included in the Study After a PSA Test and Ultrasound for Rule Out of prostate cancer. Subsequently, Testosterone and SHBG Test, PFT test, 6min-walk, O2saturation, CAT Score and BMI were be Performed in All Patients. Every 2 weeks, Testosterone Enanthate will be Injected for 16 Weeks to the Test Group and will be Given placebo to the Control Group and the Results will be Reviewed.

Participants/Inclusion and exclusion criteria

After Completing the Informed Consent Form, 80 men less than 80 Years old with COPD were Randomly Assigned into two Groups of 40 Testosterone and Placebo. Patients should not have Exacerbation Attacks at least 4 weeks Before Starting Treatment, Congestive Heart Disease, Severe Uncontrol Hypertension, Venous Thrombosis, History of Thromboembolism, History of Coagulation Disorders, Polycythemia and Prostate Cancer.

Intervention groups

The Intervention will be Performed with 100 mg Testosterone Enanthate Which will be Injected every 2 Weeks for 16 Weeks. For the Control Group, a Drug Solvent, Which is Generally a Basic Substance in all Drugs (NaCl) and Harmless, will be Used in the Same

Vials for the Placebo.

Main outcome variables

Changes in hormonal tests, PFT, 6min-walk, Improvement in O2saturation, CAT score, and Changes in BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180805040708N1**
Registration date: **2018-08-28, 1397/06/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-28, 1397/06/06**

Update count: **0**

Registration date

2018-08-28, 1397/06/06

Registrant information

Name

Somayeh Mortazavi Moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7687 1570

Email address

s.mortazavi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Testosterone on Pulmonary Function in Male with Chronic Obstructive Pulmonary Disease

Public title
Effect of Testosterone in COPD

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All Male Patients With Chronic Obstructive Pulmonary Disease
Exclusion criteria:
Exacerbation In the Last 4 Weeks Congestive Heart Disease Sever Uncontrol Hypertention Thromboembolic Disease Coagulation Disorders Polycythemia Prostate Cancer History

Age
To 80 years old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization With Website: Randomization.com

Blinding (investigator's opinion)
Double blinded

Blinding description
The Study is Double Blind , so that the Participants, Principal Researcher, Clinical Care, Data Analyzer are not Aware of Grouping Results.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Amir Al-Momenin Hospital, Sardasht square

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.ARAKMU.REC.1396.245

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes

1

Description

Pulmonary Function test

Timepoint

Performing a pulmonary function test at the beginning of the study before the start of the intervention and 16 weeks after receiving testosterone.

Method of measurement

Spirometry

Secondary outcomes

1

Description

Body mass index

Timepoint

Measurement of Body Mass Index at the beginning of the study before the intervention and 16 weeks after receiving testosterone

Method of measurement

Based on height and weight

2

Description

6 min-walk distance

Timepoint

Measurement of 6 min-walk distance at the beginning of

the study before the intervention and 16 weeks after receiving testosterone

Method of measurement

Meter

3

Description

o2 saturation

Timepoint

Measurement of Pulse Oximetry at the Beginning of the Study Before the Intervention and 16 weeks after Receiving Testosterone

Method of measurement

Pulse Oximetry

Intervention groups

1

Description

Intervention group: Testosterone Enanthate will be Injected 100 mg every 2 Weeks for 8 Courses

Category

Treatment - Drugs

2

Description

Control group: For the Control Group, a Drug Solvent, Which is Generally a Basic Substance in all Drugs (NaCl) and Harmless, will be Used in the Same Vials for the Placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Momenin Hospital

Full name of responsible person

Mortazavi Moghadam Somayeh

Street address

Amir Al Momenin Hospital, Sardasht square

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3848176941

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+98 86 3417 3601

Email

s.mortazavi@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

Street address

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arjomandzadegan@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Somayeh Mortazavi Moghadam

Position

Internal medicine assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Amir Al-Momenin Hospital, Sardasht Square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Somayeh Mortazavi Moghadam

Position

Internal medicine assistant

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

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When the data will become available and for how long

.

To whom data/document is available

.

Under which criteria data/document could be used

.

From where data/document is obtainable

.

What processes are involved for a request to access data/document

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Comments