

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the effect of oral tadalafil with and without vitamin D on the treatment of male erectile dysfunction

Protocol summary

Study aim

Determining the effect of oral vitamin D intake on the treatment of erectile dysfunction

Design

A clinical trial with a control group, with parallel groups, single blind, phase 3 on 122 patients, Sealed envelope will be used for randomization.

Settings and conduct

This study will be conducted at Urology department of Shahid Beheshti Hospital in Hamadan. The study population will be married men over 18 years of age who have erectile dysfunction and vitamin D deficiency. The study will be of single blind type, the person who evaluates the outcome of the treatment will be unaware of the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Erectile dysfunction; age over 18 years; serum vitamin D level less than 20 ng/ml; being married. Exclusion criteria: Any contraindications for taking tadalafil; cardiovascular diseases; chronic headaches and migraines

Intervention groups

Intervention group: They will take a 5 mg tablet of Tadalafil along with a 1000 IU vitamin D3 tablet daily for 3 months. Control group: They will take one 5 mg tablet of tadalafil without vitamin D3 daily for 3 months.

Main outcome variables

The main outcome will be the improvement of erectile dysfunction and the secondary outcome is an increase in serum vitamin D levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N34**

Registration date: **2024-01-23, 1402/11/03**

Registration timing: **prospective**

Last update: **2024-01-23, 1402/11/03**

Update count: **0**

Registration date

2024-01-23, 1402/11/03

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0097

Email address

a.moradi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral tadalafil with and without vitamin D on the treatment of male erectile dysfunction

Public title

The effect of oral vitamin D on erectile dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

اختلال نعوظ Age above 18 years being married Serum vitamin D level less than 20 ng/ml

Exclusion criteria:

Having a contraindication for tadalafil Having cardiovascular diseases Chronic migraine headache

Age

From **18 years** old

Gender

Male

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, sealed envelopes will be used for randomization. For this purpose, 122 cards will be prepared and on 62 the letter I will be written, meaning intervention, and on the other 62, the letter C will be written, meaning the control group. each will be put inside an envelope with aluminum foil and put them inside a box with their lids glued. At the time of patient arrival, one of the envelopes randomly will be selected and opened, and based on selected letter (I or C) patients will be assigned to intervention or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person who evaluates the outcome of the treatment will be blind to the type of groups the patients belong to.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamadan University of Medical Science

Street address

Shahid Fahmideh avenue

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Postal code

6517838697

Approval date

2023-12-31, 1402/10/10

Ethics committee reference number

IR.UMSHA.REC.1402.621

Health conditions studied**1****Description of health condition studied**

Male erectile dysfunction

ICD-10 code

N52

ICD-10 code description

Male erectile dysfunction

Primary outcomes**1****Description**

Erectile Function

Timepoint

Before intervention and 3 months after treatment

Method of measurement

The International Index of Erectile Function

Secondary outcomes**1****Description**

Change in the serum level of vitamin D

Timepoint

Before treatment and 3 months after treatment

Method of measurement

Blood serum test

Intervention groups**1****Description**

Intervention group: Consumption of Tadalafil 5 mg tablets daily along with one vitamin D3 1000 IU tablet for 3 months.

Category

Treatment - Drugs

2**Description**

Control group: Consumption of Tadalafil 5 mg tablets daily without Vitamin D for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Behzad Mohammad Souri

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Eram Blvd, Ghaem Sq, Hamedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Reza Shokohi

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vc_research@umsha.ac.ir

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Urologist MD

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Specialist

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Latest degree

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared except for authors names

When the data will become available and for how long

From Nov 2024 onwards it is permissible

To whom data/document is available

Clinical professionals and Researchers in all fields

Under which criteria data/document could be used

For treatment of patients and develop research and science

From where data/document is obtainable

Correspond to the email address of the scientific responsible for the study

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

Sending email to the scientific supervisor of the study

Comments