Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Name of organization / entity
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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 Univercity of Medical Science

Street address
Shahid Fahmideh avenue

City
Hamadan

Province
Hamadan

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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
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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
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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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