Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

The effectiveness of vitamin D deficiency in the treatment of patients with erectile dysfunction

Protocol summary

Study aim
The effectiveness of vitamin D deficiency in the treatment of patients with erectile dysfunction
Design
A three blind parallel randomized clinical trial with a control group performed on 40 patients.
Settings and conduct
In this study ED patients that refer to Ghaem and Emam Reza hospitals of Mashhad will be evaluated. Patients with serum level of vitamin D 10-30 ng/dl are enrolled to the study and are scored according to International index erectile function (IIEF) questionnaire. They are randomly assigned to either intervention or control group and after 10 weeks, the erection status is re-evaluated through the questionnaire.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Erectile dysfunction (ED) patients with serum level of vitamin D 10-30 ng/dl, patient satisfaction
Exclusion criteria: Consumers of vitamin D supplementation over the past 6 months, patients that have ED due to trauma, having neurogenic diseases like Multiple Sclerosis (MS), Amyotrophic Lateral Sclerosis (ALS)
Intervention groups
Intervention group: Routine Tadalafil with a dose of 20 mg and vitamin D supplement (Perl 50000 units of vitamin D per week for 10 weeks) is prescribed. Control group: Routine Tadalafil with a dose of 20 mg and placebo is prescribed.
Main outcome variables
Measuring the severity of erectile dysfunction

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180930041188N1**
Registration date: **2019-02-03, 1397/11/14**
Registration timing: **prospective**

Last update: **2019-02-03, 1397/11/14**
Update count: **0**
Registration date
2019-02-03, 1397/11/14

Registrant information
Name
Naeimeh Farhangnezhad
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3882 8888
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-04-21, 1398/02/01
Expected recruitment end date
2021-03-10, 1399/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of vitamin D deficiency in the treatment of patients with erectile dysfunction

Public title
The effectiveness of vitamin D deficiency in the treatment of patients with erectile dysfunction
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Erectile dysfunction (ED) Patients with vitamin D deficiency with a serum level of vitamin D 10-30 nano gram/deciliter (ng/dl) Patients satisfaction

Exclusion criteria:

Consumers of vitamin D supplementation over the past 6 months Patients that have ED due to trauma Having neurogenic diseases like Multiple Sclerosis (MS), Amyotrophic Lateral Sclerosis (ALS)

Age

No age limit

Gender

Male

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this purposive sampling, Subjects are divided into two groups of intervention and control by simple randomization and table of random numbers. In order to hide the random assignment, the method of sealed envelopes is used which the type of treatment for each patient is written in tabs as a code (odd and even numbers). Each code will placed in sealed envelopes and once a patient enters the study, physician take an envelope respectively and notes the patient's name and contact number.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is a triple blind study. Physician take an envelope, respectively which is blind to the patient's assigned group. According to the assigned number (odd or even numbers), the relevant drug of its therapeutic line is given to the patient. The researcher records the delivered drug code. Patients are also unaware of their treatment group. After completion of the treatment and collecting the data, the analyzer analyzes the data based on their code (odd or even). Evaluators and analyzer will be unaware of the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi),Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-12-18, 1397/09/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.566

Health conditions studied

1

Description of health condition studied

Erectile dysfunction

ICD-10 code

N48

ICD-10 code description

Other disorders of penis

Primary outcomes

1

Description

Measuring the severity of erectile dysfunction

Timepoint

At the beginning and after the completion of the study (10 weeks after the administration of vitamin D supplementation).

Method of measurement

The international index of erectile function questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients receive routine Tadalafil with a dose of 20 mg and vitamin D supplement (Perl 50000 units of vitamin D per week for 10 weeks).

Category

Treatment - Drugs

2

Description
Control group: patients receive routine Tadalafil with a dose of 20 mg and placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Raza hospital
Full name of responsible person
Naeimeh Farhangnezhad
Street address
Imam Reza hospital, Imam Reza Square, Ebn_e_Sina Avenue
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2

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Alireza Akhavan Rezayat
Street address
Ghaem hospital, Ahmad Abad Ave
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AkhavanRA@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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9138813944
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+98 51 3841 2081
Email
ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Naeimeh Farhangnezhad
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

Contact
Name of organization / entity

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Full name of responsible person
Alireza Akhavan Rezayat

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Urology

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Person responsible for updating data

Contact

Name of organization / entity
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Position
Student

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Medical doctor

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General Practitioner

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Email
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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data can be shared after patients are made unidentifiable.

When the data will become available and for how long
Data can be accessible 6 months after results are published.

To whom data/document is available
Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used
Carrying out analysis on data is permitted.

From where data/document is obtainable
Data can be accessible through sending an email to the corresponding author.

What processes are involved for a request to access data/document
After sending a request email to the corresponding author, data will be sent in 1 month.

Comments