

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 51 3882 8888

Email address

farhangnn911@mums.ac.ir

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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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