

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of vitamin D supplementation on androgen hormones, sperm motility, and morphology in patients with sperm motility disorder and vitamin D deficiency.

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effect of vitamin D supplementation on androgen hormones, sperm motility, and morphology in patients with sperm motility disorder and vitamin D deficiency.

##### Design

In this study, 44 patients are chosen who have inclusion criteria. participant were randomly allocated to two intervention and placebo groups and given code to each of theme.

##### Settings and conduct

A randomized double-blind clinical trial was conducted in men with sperm motility disorder who referred to Research Institute for Reproductive science.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: The desire to participate in the study - men aged 20-45 years old - Passing for at least one year from the time you decide to have a baby and not use contraceptives - sperm motility disorder according to WHO criteria - Not using vitamin D supplements and calcium in the last 3 months- levels of 25 hydroxyvitamin D (25OHD) less than 30 ng / ml exclusion criteria: unwillingness to participate - Having varicocele - individuals with azoospermia, cryptorchidism, and microorchidism - History of vasectomy

##### Intervention groups

In this study, 44 men with sperm motility disorder are selected and entered into the study according to inclusion criteria, and divided into two groups of 22 responders receiving placebo. The participants will be randomized using statistical package for social sciences (SPSS) to receive either vitamin D or placebo supplementation that is identical in terms of appearance, taste colour.

##### Main outcome variables

sperm motility, morphology and concentration, total testosterone, SHBG

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120913010826N29**

Registration date: **2018-04-29, 1397/02/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-29, 1397/02/09**

Update count: **0**

##### Registration date

2018-04-29, 1397/02/09

##### Registrant information

##### Name

Azadeh Nadjarzadeh

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 202 2817

##### Email address

azadnajarzadeh@ssu.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Shahid Sadoughi University of Medical Sciences

##### Expected recruitment start date

2017-10-16, 1396/07/24

##### Expected recruitment end date

2018-10-16, 1397/07/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of vitamin D supplementation on androgen hormones, sperm motility, and morphology in patients with sperm motility disorder and vitamin D deficiency.

**Public title**

The effect of vitamin D supplementation in people with sperm motility disorder

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The desire to participate in the study - men aged 20-45 years old - Passing for at least one year from the time that decide to have a baby and not use contraceptives - sperm motility disorder according to WHO criteria - Not using vitamin D supplements and calcium in the last 3 months- levels of 25 hydroxyvitamin D (25OHD) less than 30 ng / ml

**Exclusion criteria:**

unwillingness to participate - Having varicocele - individuals with azoospermia, cryptorchidism, and microorchidism - History of vasectomy

**Age**

From **20 years** old to **45 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using the randomized code obtained from the SPSS

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Prescribing supplement and placebo by a researcher without knowledge of its type, as well as taking it by the participants in the study without their knowledge. In order to minimize bias in the intervention, one researcher randomly assigns random access to the patient in a randomized manner, without any knowledge of the patient's condition, and the other investigator who is associated with the patient, will place that person in the designated group.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Shahid Sadoughi University of Medical Sciences

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Campus of Sadoughi University of Medical Sciences, Shohadaye Gomnam Blv, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173160

**Approval date**

2017-08-06, 1396/05/15

**Ethics committee reference number**

IR.SSU.SPH.REC.1396.87

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

asthenozoospermia

**ICD-10 code**

N46

**ICD-10 code description**

Male infertility

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

sperm motility

**Timepoint**

Before and after intervention

**Method of measurement**

Semen sample

**2****Description**

Total testosterone

**Timepoint**

Before and after intervention

**Method of measurement**

Blood sample

**3****Description**

Sex hormone binding globulin

**Timepoint**

Before and after intervention

**Method of measurement**

Blood sample

## 4

### **Description**

Free androgen index

### **Timepoint**

Before and after intervention

### **Method of measurement**

Total testosterone / SHBG

## 5

### **Description**

Sperm morphology

### **Timepoint**

Before and after intervention

### **Method of measurement**

Semen sample

## 6

### **Description**

sperm concentration

### **Timepoint**

Before and after intervention

### **Method of measurement**

Semen sample

## **Secondary outcomes**

## 1

### **Description**

Body Fat percent

### **Timepoint**

Before and after intervention

### **Method of measurement**

by body composition analyzer

## 2

### **Description**

Weight

### **Timepoint**

Before and after intervention

### **Method of measurement**

by body composition analyzer

## 3

### **Description**

Body mass index

### **Timepoint**

Before and after intervention

### **Method of measurement**

kg/m<sup>2</sup>

## 4

### **Description**

Muscle mass percent

### **Timepoint**

Before and after intervention

### **Method of measurement**

by body composition analyzer

## 5

### **Description**

waist circumference

### **Timepoint**

Before and after intervention

### **Method of measurement**

Meter

## 6

### **Description**

hip circumference

### **Timepoint**

Before and after intervention

### **Method of measurement**

Meter

## 7

### **Description**

vitamin D

### **Timepoint**

Before and after intervention

### **Method of measurement**

blood sample

## **Intervention groups**

## 1

### **Description**

In the intervention group, a dose of 50,000 units of vitamin D was administered for 12 weeks (one per of vitamin D per week for 8 weeks and only one per of vitamin d administered as a maintenance dose in the last 4 weeks)

### **Category**

Treatment - Drugs

## 2

### **Description**

In the control group, placebo was administered for 12 weeks (one placebo per week for 8 weeks and only one placebo administered in the last 4 weeks)

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Research Institute of Reproductive Sciences

#### **Full name of responsible person**

Azadeh Nadjarzadeh

#### **Street address**

Department of nutrition, school of public health,

shahid sadoughi university of medical sciences, Yazd,  
Iran

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Amir Hoshangh Mehrparvar

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azadehnajarzadeh@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Alireza Gheflati

**Position**

MSc student of public nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

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آدرس خیابان Department of nutrition, school of public  
health,shahid sadoughi university of medical  
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## Person responsible for scientific inquiries

**Contact**

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Yazd University of Medical Sciences

**Full name of responsible person**

Azadeh Najarzadeh

**Position**

PhD in Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to  
make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

Undecided - It is not yet known if there will be a plan to  
make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Data report will be shared after publishing the paper.

**When the data will become available and for how  
long**

Six months after publish

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

Using for Meta-analysis

**From where data/document is obtainable**

Center nutrition, public health, univercity of medical  
sciences yazd Tel: 009835 31492239 Email:  
azadehnajarzadeh@gmail.com Azadenadjarzadeh

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

It will be sent two weeks after the receipt of the email  
with the consent of the co-workers

**Comments**