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
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Name of organization / entity
Shahid Sadoughi University of Medical Sciences

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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

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

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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/m2

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 perl of vitamin D per week for 8 weeks and only one perl 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
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Department of nutrition, school of public health,

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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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Yazd, shohadaye gomnam Blvd, Shahid Sadoughi University of Medical Sciences

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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
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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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 sciencies 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