

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

The effect of vitamin D supplementation on spermatogram, seminal and serum levels of oxidative stress indices in idiopathic oligoasthenospermia infertile men: triple blind clinical trial

Protocol summary

Study aim

The effect of vitamin D supplementation on spermatogram, seminal and serum levels of oxidative stress indices in idiopathic oligoasthenospermia infertile men

Design

Clinical controlled trial, with parallel groups, triple blind and randomized

Settings and conduct

Present study is a triple blind randomized controlled clinical trials that will be done on idiopathic oligoasthenospermia infertile patients with deficient or insufficient levels of vitamin D referring to the urologist in Jihad daneshgahi Infertility Center in Ahvaz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willing to participate in the study and filling out the informed consent form; no conception after 12 months intercourse without any contraception; 20-49 y.o.; idiopathic oligoasthenozoospermia according to WHO criteria; vitamin D levels ≤ 30 ng, ml; Normal hormonal profile. Exclusion criteria: any known causes of infertility; any chronic disease and surgery in GU tract; any antioxidant supplements consumption, drug treatment or alcohol consumption during last 3 months; candidate for ICSI (sperm injection inside the cytoplasm); contact with pesticides, heavy metals and solvents; severe physical activity and body mass index (BMI) higher than 30 and less than 18.5 kg,m2.

Intervention groups

Patients in the intervention group will receive vitamin D tablet at a dose of 4,000 units per day for 12 weeks. Patients in the placebo group, will receive placebo tablets which is apparently similar to vitamin D, but contains maltodextrin.

Main outcome variables

Serum and seminal Total antioxidant capacity (TAC) and Malondialdehyde (MDA); seminal fluid 8-Hydroxy Deoxy

guanosine concentration (8-OHDG); seminal fluid calcium and spermatozoa intracellular calcium; serum Levels of vitamin D (25 hydroxyvitamin D), calcium, phosphorus and parathormone

General information

Reason for update

Changing the sampling completion date. Due to the lack of timely completion of the intervention because of the coronavirus prevalence sampling was delayed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20151128025274N4**

Registration date: **2018-03-28, 1397/01/08**

Registration timing: **prospective**

Last update: **2020-06-18, 1399/03/29**

Update count: **1**

Registration date

2018-03-28, 1397/01/08

Registrant information

Name

Ahmad Zare Javid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8319

Email address

zarejavid-a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-29, 1397/02/09

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on spermatogram, seminal and serum levels of oxidative stress indices in idiopathic oligoasthenospermia infertile men: triple blind clinical trial

Public title

The effect of vitamin D supplementation on male infertility

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willing to participate in the study and filling out the informed consent form They should be infertile (no conception after 12 months intercourse without any contraception) Age 20-49 y.o. Idiopathic oligoasthenozoospermia according to WHO criteria Vitamin D levels ≤ 30 ng, ml Normal hormonal profile

Exclusion criteria:

Any known causes of infertility (such as infection in genitourinary (GU) tract, anatomical abnormality in GU tract, immunological and etc.) Any chronic disease and any surgery in GU tract Any antioxidant supplements consumption, drug treatment or alcohol consumption during last 3 months Candidate for ICSI (sperm injection inside the cytoplasm) Contact with pesticides, heavy metals and solvents Severe physical activity and body mass index (BMI) higher than 30 and less than 18.5 kg,m2

Age

From **20 years** old to **49 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients in each of the study groups (supplements or placebo) will be done by statistical software using classified randomized blocking method (4 blocks) based on age (20 to 40 and 40 to 49) and sperm concentration (5-15 and 15-20 million per milliliter). In addition, in order to reduction selection bias error, allocation concealment will be used. This will be done by

assigning unit codes to each person's drugs.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to reduction selection bias error, allocation concealment method will be used.This will be done by assigning unit codes to each person's drugs. In this way, the participants, the researcher and the statistical analyst, will be kept blind to assignment of the study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Highway, Deputy of Research and Technology; Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715751

Approval date

2018-02-23, 1396/12/04

Ethics committee reference number

IR.AJUMS.REC.1396.1013

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

Male Infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

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

Total sperm count

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Spermatogram

2**Description**

Sperm Motility

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Spermatogram

3**Description**

Serum and seminal Total Antioxidant Capacity

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

ELISA

4**Description**

Serum and seminal Malondialdehyde

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

ELISA

5**Description**

Seminal 8-hydroxy Deoxy guanosine

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

ELISA

6**Description**

Serum 25 hydroxyvitamin D

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

ELISA

7**Description**

Serum and seminal calcium

Timepoint

Before the start of the intervention and 12 weeks after the intervention

Method of measurement

Calorimetry

8**Description**

Serum phosphate

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Calorimetry

9**Description**

Spermatozoa intracellular calcium

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

ELISA

10**Description**

Serum Parathormon

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients in the intervention group will receive vitamin D supplementation (in tablet form) at a dose of 4,000 units per day for 12 weeks. Vitamin D supplementation will be provided by Ahvaz Jundishapur Pharmaceutical Technology Development Center.

Category

Treatment - Drugs

2**Description**

Control group: Patients in the control group will receive placebo (in tablet form) per day for 12 weeks. Placebo tab is apparently similar to the vitamin D supplement, but containing maltodextrin. The placebo will be provided by the Ahvaz Jundishapur Pharmaceutical Technology Development Center.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Infertility research and treatment center of ACECR
Khouzestan

Full name of responsible person

Ahmad Zare Javid

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Leila Maghsoumi-Norouzabad
Position
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Latest degree
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Person responsible for updating data

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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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