

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\leq$  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  $\leq$  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**

Khuzestan

**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

**Street address**

Golestan Highway, Ahvaz University of Medical  
Sciences

**City**  
Ahvaz  
**Province**  
Khouzestan  
**Postal code**  
6135715751  
**Phone**  
+98 61 3373 8330  
**Fax**  
**Email**  
ahmaddjavid@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Dr. Mohammad Badavi  
**Street address**  
Golestan Highway, Ahvaz Jundishapur University of  
Medical Sciences  
**City**  
Ahvaz  
**Province**  
Khouzestan  
**Postal code**  
6135715751  
**Phone**  
+98 61 3373 8330  
**Email**  
badavim@yahoo.com

#### 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**  
Ph.D Student

**Latest degree**  
Master  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
Golestan Highway, Ahvaz Jundishapur University of  
Medical Sciences  
**City**  
Ahvaz  
**Province**  
Khouzestan  
**Postal code**  
6135715751  
**Phone**  
+98 61 3373 8330  
**Email**  
l.maghsumi55@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Ahmad Zare Javid  
**Position**  
Associated professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
Golestan Highway, Ahvaz Jundishapur University of  
Medical Sciences  
**City**  
Ahvaz  
**Province**  
Khouzestan  
**Postal code**  
6135715751  
**Phone**  
+98 61 1373 8330  
**Email**  
ahmaddjavid@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Leila Maghsoumi-Norouzabad  
**Position**  
Ph.D Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
Golestan Highway, Ahvaz Jundishapur University of  
Medical Sciences

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715751

**Phone**

+98 61 3373 8330

**Email**

l.maghsumi55@gmail.com

**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