Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Oct 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 Jahad 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 sampeling completion date. Due to the lack of timely completion of the intervention because of the coronavirus prevalence sampeling 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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Golestan Highway, Ahvaz University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Badavi
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Golestan Highway, Ahvaz Jundishapur 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
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
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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