

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The Effect of Oral Vitamin D3 Supplementation on Spermogram Quantitative and Qualitative Indicators in Infertile Male

Protocol summary

Summary

(1) Objectives: The aim of this study is to determine the effect of Oral Vitamin D3 Supplementation on Spermogram Quantitative and Qualitative Indicators in Infertile Male.(2) Design: Participations are divided into 2 groups(intervention and control).(3) Setting and Conduct:in this study 60 subjects 20-45 years of infertile men with abnormal spermogram undergoing infertility treatment.(4) inclusion criteria: body mass index is 18/5-30; not to intake any vitamin D3 at therapeutic doses in last 3 months; having disrupt sperm of unknown origin(idiopatic); the serum level of vitamin D3 should be less than 30 or equal to 30 Ng in liter; lack of anatomical abnormalities of the genital tract such as varicocele grade two and above, Testes and vas deferens history of surgery.exclusion criteria: not taking more than one dose of vitamin D3; the existence of some signs or symptoms wich prohibit the continuous of using according to urologist and nutritionnist; start taking other supplements drugs that have been banned their entry criteria during the study.(5) interventions. intervention group: the supplement of vitamin D3 for 12 weeks (each week 1 pill of supplement vitamin D3 for 8 weeks and in remaining 4 weeks 1 supplement vitamin D3 pill as a maintenance dose). control group: Placebo of vitamin D3 for 12 weeks (each week 1 pill of Placebo vitamin D3 for 8 weeks and in remaining 4 weeks, 1 pill of Placebo vitamin D3 as a maintenance dose).(6) outcomes studied: Quantitative and qualitative indicators of sperm and hormones related to spermatogenesis in Infertile Mails.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111830947N1**

Registration date: **2017-04-02, 1396/01/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-02, 1396/01/13

Registrant information

Name

Afsaneh Talebi

Name of organization / entity

Iran University of Medical Sciences, School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 26 3340 1207

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Oral Vitamin D3 Supplementation on Spermogram Quantitative and Qualitative Indicators in Infertile Male

Public title

The Effect of Oral Vitamin D3 Supplementation on

Spermogram Quantitative and Qualitative Indicators in Infertile Male

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: Be healthy physically and mentally : older than 20 years and less than 45 years: body mass index is 18/5-30: not to intake any vitamin D3 at therapeutic doses in last 3 months: not to intake supplementation in non_therapeutic doses in last 3 months: not to intake medications that influence on the level of vitamin D3 includes, glucocorticoids and anti convulsion: the drugs that influence on spermatogenesis such as cimetidine, spirinolactone should not have be used according to urologist in last 3 months: lack of Azoospermia in spermogram: having disrupt sperm of unknown origin(idiopatie): lack of genital tract infection or drug treatment in this regard during the past three months according to the clinical records and according to patients saying: lack of anatomical abnormalities of the genital tract such as varicocele grade two and above, Testes and vas deferens history of surgery: no contact with pesticides, heavy metals and high temperature: not using cigarette or hookah in last 3 month: not using alcohol or narcotic: the serum level of vitamin D3 should be less than 30 or equal to 30 Ng in liter: no disorder in prolactine levels or TSH. exclusion criteria: not taking more than one dose of vitamin D3: the existence of some signs or symptoms wich prohibit the continuous of using according to urologist and nutritionnist: start taking other supplements drugs that have been banned their entry criteria during the study

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: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

School of nursing and midwifery, Yasemi Rashid street, Valiasr street, Tehran

City

Tehran

Postal code

Approval date

2016-12-14, 1395/09/24

Ethics committee reference number

IR.IUMS.REC 1395.9311373019

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

n46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Spermogram Qualitative Indicators

Timepoint

Patients are tested twice for Spermogram Qualitative Indicators.(one day before the first day of training – one day after the final day training course).

Method of measurement

Spermogram

2

Description

Spermogram Quantitative Indicators

Timepoint

Patients are tested twice for Spermogram Quantitative Indicators.(one day before the first day of training – one day after the final day training course).

Method of measurement

Spermogram

Secondary outcomes

1

Description

Hormonal markers related to spermatogenesis(LH, FSH, TT, FT, SHBG

Timepoint

Patients are tested twice for Hormonal markers related to spermatogenesis.(one day before the first day of

training – one day after the final day training course).

Method of measurement

Evaluation of serum levels

Intervention groups

1

Description

Intervention group: the supplement of vitamin D3 for 12 weeks (each week 1 pill of supplement vitamin D3 for 8 weeks and in remaining 4 weeks 1 supplement vitamin D3 pill as a maintenance dose

Category

Treatment - Drugs

2

Description

control group: Placebo of vitamin D3 for 12 weeks (each week 1 pill of Placebo vitamin D3 for 8 weeks and in remaining 4 weeks, 1 pill of Placebo vitamin D3 as a maintenance dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

AkbarAbadi Hospital in Tehran

Full name of responsible person

Afsaneh Talebi

Street address

AkbarAbadi Hospital in Tehran, Ferdose garden station, Molavi street, Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Urology Clinic Doctor Said Sahebkhaf

Full name of responsible person

Afsaneh Talebi

Street address

Urology Clinic Doctor Said Sahebkhaf, Sabounchi Street, Beheshti Martyr Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Morteza Naserbakht

Street address

Iran University of Medical Sciences, Next to Milad tower, Hemmat highway, Tehran.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences, School of Nursing and Midwifery

Full name of responsible person

Afsaneh Talebi

Position

MSc Student of Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

Street address

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