

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the effect of vitamin D therapy on asthenospermia in infertile patients with vitamin D insufficiency

Protocol summary

Study aim

Evaluation of the effect of vitamin D therapy on asthenospermia in infertile patients with vitamin D insufficiency who refer to Ghaem Hospital's medical clinics

Design

Clinical trial with control and intervention group, with parallel, two-way blind, randomized groups

Settings and conduct

Patients with asthenospermia referred to the treatment clinics of Ghaem Hospital in Mashhad. Patients with asthenospermia and insufficiency of vitamin D are included in the study. Patients with serum levels below 20 (deficiency) are excluded from the intervention and are recommended to complete treatment for vitamin D deficiency. After exclusion criteria and randomized patients (using simple computer randomization), patients are divided into two groups. In the control group, common treatments are performed to correct spermogram. And for vitamin D insufficiency, It is only recommended to change and correct the lifestyle. In the intervention group, In addition to the items listed in the control group, With vitamin D Perl, is taken at a dose of 5,000 units per week for up to 8 weeks. After three months, vitamin D levels are measured again in both groups. Six months after the start of the study, Again vitamin D levels and new spermograms in both groups will be compared and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion of Criteria: 1. Asthenospermia. 2. Insufficient vitamin D. 3- Age 18-50 Exclusion criteria: Existence of other organic diseases such as varicocele, Genetic disorder and clinical syndrome

Intervention groups

In the intervention group, in addition to routine infertility treatments, vitamin D deficiency is treated with prescription vitamin D perl and its effect on spermogram is investigated. In the control group, only routine infertility treatments are performed.

Main outcome variables

Correction of asthenospermia; Correction of vitamin D insufficiency; Correction of infertility.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200412047046N1**

Registration date: **2020-04-25, 1399/02/06**

Registration timing: **retrospective**

Last update: **2020-04-25, 1399/02/06**

Update count: **0**

Registration date

2020-04-25, 1399/02/06

Registrant information

Name

Iman Broomand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3843 2256

Email address

broumandi951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-08-23, 1398/06/01

Actual recruitment end date

2020-03-10, 1398/12/20
Trial completion date
2020-03-10, 1398/12/20

Scientific title
Evaluation of the effect of vitamin D therapy on asthenospermia in infertile patients with vitamin D insufficiency

Public title
Investigation of the effect of vitamin D treatment on asthenospermia in infertile patients with vitamin D insufficiency

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Asthenospermia Vitamin D insufficiency (20-30) Age 18-50
Exclusion criteria:
Normalization levels of vitamin D in the control group
The presence of other organic diseases such as varicocele and genetic disorders and clinical syndrome

Age
From **18 years** old to **50 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **65**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization Randomization Method: Excel software or other randomization websites. Allocation Concealment: Opaque envelope

Blinding (investigator's opinion)
Double blinded

Blinding description
1-Participants do not know are they In which group. 2- Evaluators do not know the data belongs to which group

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghoreisi building, next to Hoveize cinema, Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-08-13, 1398/05/22

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.432

Health conditions studied

1

Description of health condition studied

Asthenospermia; Vitamin D insufficiency

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Asthenospermia (sperm motility factor in WHO criteria for motility less than a + b <30)

Timepoint

perform spermograms at the beginning of the study and then six months later

Method of measurement

To perform a spermogram, should be performed at least 3 days and maximum 5 days after the last ejaculation .

The patient's spermogram will be tested in a same reference center by an experienced operator

2

Description

Insufficiency of vitamin D (between 20-30)

Timepoint

At the beginning of the study, three and a six months later

Method of measurement

In these patients, serum levels of vitamin D are measured through Anterior veins of the forearm from a blood sample.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: In addition to prescribing routine infertility treatments, prescribing Perl Vitamin D 5,000 units once a week for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: In the control group, routine infertility treatments are performed and The patient is also advised to change their lifestyle to improve their vitamin D levels by sunbathing and changing their diet.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Gaem hospital

Full name of responsible person

Alireza Akhavanrezayat

Street address

Urology department, Ghaem hospital, Ahmad abad Ave.

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Province

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Postal code

99199-91766

Phone

+98 51 3843 2256

Email

Akhavanra@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreishi building, next to Hoveize cinema, Daneshgah Ave.

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Phone

+98 51 3841 1538

Email

vcresraech@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Alireza Akhavanrezayat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Urology department, Ghaem hospital, Ahmad abad Ave.

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Phone

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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After making participants unrecognizable, all variables can be shared

When the data will become available and for how long

Start of access period from 1400 (2021, April)

To whom data/document is available

The data of this study will be available to all people in different environments and in related fields.

Under which criteria data/document could be used

Data should be used to produce science. Data should be used to improve treatment conditions.

From where data/document is obtainable

1) Dr. Alireza Akhavanrezayat; e-mail: akhavana@mums.ac.ir. 2) Dr. Iman Broomand; e-mail: iman.broomand@icloud.com

What processes are involved for a request to access data/document

After the mentioned time, regarding the availability of data, the applicant can announce her request by e-mail and receive a response within 3 months.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Alireza Akhavanrezayat

Position

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Latest degree

Specialist

Other areas of specialty/work

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