

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### A clinical trial to compare the effect of vitamin D supplementation on outcomes of assisted reproduction techniques in infertile women

#### Protocol summary

##### Summary

Objectives: To determine the effect of vitamin D supplementation on ovarian markers, endometrial quality and biochemical and clinical pregnancy rate. Design: Randomized, double-blind (blind to participants and experimenters), placebo-controlled, single center. Method: Inclusion criteria: Women in the age of 18 to 38 years ; having Primary infertility ; having female infertility approved by gynecologist ; using of long-term down-regulation protocol and then ovulation induction ; not using of vitamin D supplementation before the study ; not having a medical history of systemic disorders such as Cushing's syndrome, hyper or hypothyroidism, hyperprolactinemia ; no liver ,kidney and heart diseases ; having BMI Less than or equal to 30 KG/M2 or More than or equal to 18.9 KG/M2 ; not having clinical signs of vitamin D deficiency such as osteomalacia, osteoarthritis, the joint and bone pain and rheumatoid arthritis ; not using of drugs such as Phenytoin, Phenobarbital, Carbamazepine, Isoniazid, Rifampin Theophylline which may affect on vitamin D metabolism ; the absence of congenital or acquired uterine defects ; not having endometriosis. Exclusion criteria: Using surrogate uterine ; using the Oocyte donation ; Unwillingness to continue cooperation ; not having fertile follicle after injection of gonadotropin hormone. The total sample size: 85 cases. 42 cases in the intervention group and 43 cases in the control group. Intervention: 50000 units of vitamin D as a gelatin capsule was given weekly for 6 weeks to the intervention group and one placebo as a gelatin capsule was given weekly for 6 weeks to the control group. outcome: Improvement in the number of oocytes , the embryos quality , the endometrium quality, and the incidence of clinical and biochemical pregnancy rates.

#### General information

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2015111124999N1**

Registration date: **2016-12-30, 1395/10/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2016-12-30, 1395/10/10

#### Registrant information

##### Name

mahboubeh taebi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7538

##### Email address

m\_taeabi@nm.mui.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

#### Expected recruitment start date

2015-03-20, 1393/12/29

#### Expected recruitment end date

2015-08-22, 1394/05/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A clinical trial to compare the effect of vitamin D supplementation on outcomes of assisted reproduction

techniques in infertile women

#### Public title

The effect of vitamin D supplementation on reproductive outcomes

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Women in the age of 18 to 38 years ; having Primary infertility ; having female infertility approved by gynecologist ; using of long-term down-regulation protocol and then ovulation induction ; not using of vitamin D supplementation before the study ; not having a medical history of systemic disorders such as Cushing's syndrome, hyper or hypothyroidism, hyperprolactinemia ; no liver, kidney and heart diseases ; having BMI Less than or equal to 30 KG/M2 or More than or equal to 18.9 KG/M2 ; not having clinical signs of vitamin D deficiency such as osteomalacia, osteoarthritis, the joint and bone pain and rheumatoid arthritis ; not using of drugs such as Phenytoin, Phenobarbital, Carbamazepine, Isoniazid, Rifampin Theophylline which may affect on vitamin D metabolism ; the absence of congenital or acquired uterine defects ; not having endometriosis. Exclusion criteria: Using surrogate uterine ; using the Oocyte donation ; Unwillingness to continue cooperation ; not having fertile follicle after injection of gonadotropin hormone.

#### Age

From **18 years** old to **38 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **85**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

Participants were divided into two intervention and control groups using random numbers table.

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Hezarjarib street

##### City

Isfahan

##### Postal code

##### Approval date

2015-02-14, 1393/11/25

##### Ethics committee reference number

393794

### Health conditions studied

#### 1

##### Description of health condition studied

In vitro fertilization

##### ICD-10 code

Z31.2

##### ICD-10 code description

Admission for harvesting or implantation of ova

### Primary outcomes

#### 1

##### Description

Rate of clinical pregnancy

##### Timepoint

Four weeks after intervention

##### Method of measurement

Ultrasound

#### 2

##### Description

Rate Biochemical pregnancy

##### Timepoint

7 days after embryo transfer

##### Method of measurement

Laboratory Kit

#### 3

##### Description

rate of fertilization

##### Timepoint

16 to 18 hours after in vitro fertilization

##### Method of measurement

Microscope

#### 4

##### Description

Embryo quality

##### Timepoint

16 to 18 hours after in vitro fertilization

##### Method of measurement

Microscope

## 5

### Description

Endometrial quality

### Timepoint

At the same time oocyte retrieval

### Method of measurement

Ultrasound

## Secondary outcomes

### 1

#### Description

The number of oocytes

#### Timepoint

WHEN PICK UP

#### Method of measurement

Microscope

### 2

#### Description

Vitamin D serum after intervention

#### Timepoint

6 to 8 weeks after intervention

#### Method of measurement

Laboratory Kit

## Intervention groups

### 1

#### Description

Intervention group: Gelatin capsule of vitamin D, 50000 units, orally, once a week, for 6 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo, Gelatin capsule, orally, once a week, for 6 weeks.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan Fertility and infertility Center

##### Full name of responsible person

Dr Mohammad Hossein Nasr-Esfahani

##### Street address

No. 23, Hasht Behesht street, Salman Farsi street, Bozorgmehr square

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research of Nursing and Midwifery Faculty, Isfahan University of Medical Science

##### Full name of responsible person

Dr Ashraf Kazemi

##### Street address

Hezar jarib street

##### City

Isfahan

#### 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 of Nursing and Midwifery Faculty, Isfahan University of Medical Science

#### 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

Nursing and Midwifery faculty of Isfahan

##### Full name of responsible person

Mahboubeh Taebi

##### Position

Master of midwifery, Faculty member of Isfahan university of medical sciences

##### Other areas of specialty/work

##### Street address

Hezarjarib Street

##### City

Isfahan

##### Postal code

##### Phone

+98 31 3776 5064

##### Fax

##### Email

m\_taebi@nm.mui.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Isfahan University of Medical Sciences

**Full name of responsible person**

Sara Abedi

**Position**

Master student of midwifery

**Other areas of specialty/work**

**Street address**

No. 318, alley 3, Ragheb Isfahani street, shahid  
Bakhshi street

**City**

Isfahan

**Postal code**

**Phone**

+98 317786752

**Fax**

**Email**

abedi\_sa@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Sara Abedi

**Position**

Master student of midwifery

**Other areas of specialty/work**

**Street address**

No. 318, alley 3, Ragheb Isfahani street, shahid  
Bakhshi street

**City**

Isfahan

**Postal code**

**Phone**

+98 939 854 8815

**Fax**

**Email**

abedi\_sa@yahoo.com

**Web page address**

**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*