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, hyperprolactimenia ; 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

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Recruitment status

Recruitment complete

Funding source

Vice chanceller 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, hyperprolactimenia ; 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
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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

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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

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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