

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of vitamin D deficiency treatment on pregnancy outcomes in frozen-thawed embryo transfer cycles

Protocol summary

Study aim

The effect of vitamin D supplementation on pregnancy outcome in frozen thawed embryo transfer cycles

Design

In this randomized, not blinded, parallel, phase 2 clinical trial with control group, 114 women with vitamin D insufficiency were randomly divided into two groups using random number table.

Settings and conduct

Serum vitamin D level of patients who were candidate for frozen embryo transfer, was checked. 114 patients with serum vitamin D level less than 30 ng/ml and met the inclusion criteria were included in this study. Women were randomly divided into two groups. 57 patients, as a case group received 50000 units vitamin D supplement per oral, weekly for 8-10 weeks and serum vitamin D level is rechecked in the end of treatment. If serum vitamin D level was normal, they entered in the frozen-thawed embryo transfer cycle. 57 another patients, as a control group entered in frozen-thawed embryo transfer cycles without any intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women who want transfer cryopreserved embryos, patients with serum vitamin D level less than 30 ng/ml Exclusion criteria: more than 40 years old; less than 20 years old; history of endocrine disorder; severe endometriosis; systemic disease; repeated implantation failure; repeated abortion; congenital or acquired uterine anomaly with or without operation; donation-recipient cycles.

Intervention groups

Intervention group: Patients, as a case group received 50000 units vitamin D supplement orally, weekly for 8-10 weeks and serum vitamin D level was rechecked in the end of treatment. Control group: Women as a control group entered in frozen-thawed embryo transfer cycle without any intervention.

Main outcome variables

Chemical pregnancy

General information

Reason for update

Updating the trial according to the last changes in inclusion and exclusion criteria, actual number of cases, date of recruitment and trial completion

Acronym

IRCT registration information

IRCT registration number: **IRCT201207156420N11**

Registration date: **2013-12-24, 1392/10/03**

Registration timing: **retrospective**

Last update: **2021-04-19, 1400/01/30**

Update count: **1**

Registration date

2013-12-24, 1392/10/03

Registrant information

Name

Maryam Eftekhar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

Phone

+98 35182470856

Email address

eftekhar@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd reserch and clinical center for infertility

Expected recruitment start date

2013-09-01, 1392/06/10

Expected recruitment end date

2013-10-15, 1392/07/23

Actual recruitment start date

2013-09-01, 1392/06/10

Actual recruitment end date

2013-10-15, 1392/07/23
Trial completion date
 2014-02-28, 1392/12/09

Scientific title
 Effect of vitamin D deficiency treatment on pregnancy outcomes in frozen-thawed embryo transfer cycles

Public title
 Treatment of vitamin D deficiency in assisted reproductive cycles.

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Women who were candidate for transfer cryopreserved embryos in ART cycles Infertile women with serum vitamin D below 30ng/ml
Exclusion criteria:
 Women older than 40 years Women less than 20 years BMI >30 Kg/m2 History of endocrine disorders Severe endometriosis Systemic diseases Repeated implantation failure/repeated abortion Congenital or acquired uterine anomaly with or without surgery Women who had visible hydrosalpinx in vaginal ultrasonography Cycles with egg or embryo donation

Age
 From **20 years** old to **40 years** old

Gender
 Female

Phase
 2

Groups that have been masked
No information

Sample size
 Target sample size: **128**
 Actual sample size reached: **114**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In this randomized clinical trial, infertile women with serum vitamin D below 30ng/ml were enrolled in the study. 1 to 114 numbers were assigned to each woman who met the inclusion criteria consecutively. After giving information about the research design and signed a written consent form, women divided into two 57-participant groups by using random number table and random codes generation. Randomization was simple, individual using a random number table.

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yazd Research and Clinical Center for Infertility

Street address

Bouali Avenue, Safayeh

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

214

Health conditions studied

1

Description of health condition studied

Vitamin D3 deficiency, Female infertility treatment

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

14 days after embryo transfer

Method of measurement

Serum B-hcg

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

28 days after embryo transfer

Method of measurement

Vaginal sonography

Intervention groups

1

Description

Control: Receiving no vitamin D supplementation.

Category

Treatment - Drugs

2

Description

Intervention: In case group, the patients received 50000 units vitamin D orally every week for 8-10 weeks before starting embryo transfer cycle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Research and Clinical Center for Infertility

Full name of responsible person

Maryam Eftekhari

Street address

Bouali Avenue, Safayeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Full name of responsible person

Ali mohammad abdoli fahadan

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aliabdoli110@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd Research and Clinical Center for Infertility

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

Yazd Research and Clinical Center for Infertility

Full name of responsible person

Abbas aflatoonian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Web page address**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

All participant data sets are to be shared

When the data will become available and for how long

2 months after the result publication

To whom data/document is available

A journal in which the results are published

Under which criteria data/document could be used

Submission of an official application via the agent that is legally in charge

From where data/document is obtainable

Yazd Reproductive Sciences Institute, Bouali Ave, Yazd, Iran. 983538247085

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

Submission of an official application via the agent that is legally in charge

Comments