

# 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 Eftekhari

##### Name of organization / entity

Yazd Research and Clinical Center for Infertility

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35182470856

##### Email address

eftekhari@ssu.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Yazd research 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

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877391

**Phone**

+98 35 3824 7085

**Email**

eftekharmaryam@ssu.ac.ir

**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

**Street address**

Bouali Avenue, Safayeh

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**Province**

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**Phone**

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**Email**

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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Bouali Avenue, Safayeh

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Abbas\_aflatoonian@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Position**

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**Fax****Email**

eftekharmaryam@ssu.ac.ir

**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**