

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Evaluation of calcitriol on IVF outcome in infertile women with vitamin D deficiency refers to infertility centers in Shiraz 2014-2015

#### Protocol summary

##### Summary

The purpose of this study is evaluation of the effects of chlosteriol on IVF outcomes in infertile women. For this purpose, first, of women reffering (attending) to Shiraz infertility clinics for IVF infertility, 180 ones will be selected. After assessing the study inclusion criteria and if satisfied, persons will be included in the study. Blood samples from 180 ones will be taken and vitamin D levels in the blood samples will be determined (measured). Among them, 90 ones that have vitamin D deficiency will be enrolled into the study. Four weeks prior to IVF, control and experimental group (intervention) will be fed by determined dose of placebo and cholestriol. The IVF outcomes in groups A and B, including pregnancy tests, and observation of pregnancy style eighth weeks after embryo transfer and the pregnancy continued until twentieth weeks of pregnancy will be assessed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014030916911N1**

Registration date: **2014-08-05, 1393/05/14**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-08-05, 1393/05/14

##### Registrant information

###### Name

Bahar Morshed Behbahani

###### Name of organization / entity

Shiraz Medical University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1630 1288

###### Email address

morshed\_b@sums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Research Council of Shiraz University of Medical Sciences

###### Expected recruitment start date

2014-04-21, 1393/02/01

###### Expected recruitment end date

2014-11-22, 1393/09/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Evaluation of calcitriol on IVF outcome in infertile women with vitamin D deficiency refers to infertility centers in Shiraz 2014-2015

###### Public title

Evaluation of calcitriol on IVF outcome in infertile women with vitamin D deficiency

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Written consent; Lack of bone diseases (disorders); Lack of Kidney (renal) diseases; The absence of endocrine glands' disorders (abnormalities); Absence of chronic digestive disorders (Crohn's, colitis, ulcers, chronic diarrhea); Non-affliction to vitamin D and calcium metabolism disease that their specific effects have proven; Non-use of vitamin D and calcium supplements before entry into the study (oral use in two weeks ago and injection in the last six months); No use (Failure to

use) drugs that have significant effects on serum levels of these compounds (vitamin D and calcium), such as antiepileptics (anticonvulsant), diuretics, cardiac drugs, blood pressure medications (drugs), cimetidine, theophylline, cholestyramine; Serum calcium level less than 10/5 g/dl Exclusion criteria: Allergy to Vitamine D, vitamine D malabsorption syndrome, renal function disorder (abnormality), afflicted with hypercalcemia or vitamine D toxicity; Stop treatment (therapy), ovulation stimulation or embryo transfer for any reason; Afflicted with the disease affecting vitamin D level (renal diseases, endocrine system disorders); Afflicted with the disease affecting immunity system; Use of drugs (medicine) affecting function of immunity system ; Exposure to UV rays (radiation) subject to (with) medical and remedy (therapy) purposes; Afflicted with acute diseases recently

**Age**

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

**Gender**

Female

**Phase**

4

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **180**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences Ethics Committee

**Street address**

Shiraz University of Medical Sciences Central Building, Zand Street

**City**

shiraz

**Postal code**

1978 -71345

**Approval date**

2014-03-02, 1392/12/11

**Ethics committee reference number**

ct-92-6899

**Health conditions studied****1****Description of health condition studied**

infertility

**ICD-10 code**

n98.2

**ICD-10 code description**

Complications of attempted introduction of fertilized ovum following in vitro fertilization

**Primary outcomes****1****Description**

vitamin d level in blood

**Timepoint**

before starting the process of IVF

**Method of measurement**

sampling

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Drug Intervention group: Calcitriol tab 0.5microgram daily for 4 weeks

**Category**

Treatment - Drugs

**2****Description**

Control group: placebo administered to patients in this group for 4 weeks

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mother and Child Hospital Ghadir

**Full name of responsible person**

Mohamed Ibrahim Parsanezhad

**Street address**

Quran Gate, Mother and Child Hospital Ghadir

**City**

shiraz

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Gholamreza Hatam

**Street address**

Shiraz University of Medical Sciences Central Building,  
Zand Street

**City**

shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz University of Medical Sciences

**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**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ms.Bahar Morshed Behbahani

**Position**

Master of Midwifery

**Other areas of specialty/work****Street address**

School of Nursing and Midwifery, Namazi Square

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**Postal code****Phone**

+98 71 1212 2633

**Fax**

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**Email**

morshed\_b@sums.ac.ir

**Web page address**

### Person responsible for updating data

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ms.leila doryanzadeh

**Position**

Master of Midwifery

**Other areas of specialty/work****Street address**

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shiraz

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### 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*