

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**

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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