

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The study of the role of vitamin D3 in microinjection outcome in patients with repeated ART(Assisted Reproductive Technique) failure failure

Protocol summary

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Summary

In respect of effects of vitD3 in implantation. In this clinical trial research we are going to evaluate effects of vit D3 (Pregnancy outcome, clinical pregnancy rate)in patients with history of two or more repeated implantation failure. After excluding of other problems(Hormonal, Anatomical, Rheumatologic, Thrombophilia, genetic and male problems) and certain to no using vitamin D and Calcium from three months ago in patients, we have two groups: A)use tablet of Ca-D B.I.D twp months before ICSI(case group)n=50; B) use tablet of Ca B.I.D twp months before ICSI(control group)n=50.

Recruitment status

Recruitment complete

Funding source

Jahad Daneshghahi

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

Assisted reproductive technique

IRCT registration information

IRCT registration number: **IRCT2012120311430N2**

Registration date: **2013-04-20, 1392/01/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-04-20, 1392/01/31

Registrant information

Name

Simin Zafardoust

Name of organization / entity

Jahad University

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 4701

Email address

Scientific title

The study of the role of vitamin D3 in microinjection outcome in patients with repeated ART(Assisted Reproductive Technique) failure failure

Public title

The efficacy of vitD3 in patients with ART(Assisted Reproductive Teqchnique) failure

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: infertile women 20-35 years old with two or more previous IVF failure, without using vitamin D and Calcium from 3 months before. Exclusion criteria:untreated medical disorders; endometriosis; poor responders; hydrosalpinx in ultrasonography; abnormal semen analysis (Abnormal form>96%,A+B≤32%); use of drugs that affect on immune system; thrombophilia (homozygot PAI-I , homozygot C677T, homozygot A1908C, Heterozygot A1908C-C977T); hormonal disorder (FSH>12,PCO); anatomic disorders; genetic disorders and infective disorders

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **100****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**

Jahad of university

Street address

Shariati-Yakhchal

City

Tehran

Postal code

19419113194

Approval date

2010-03-02, 1388/12/11

Ethics committee reference number

9224/ 51/ 30/پ س

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

Patients with IVF Failure

ICD-10 code

Z31.2

ICD-10 code description

In vitro fertilization

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

Pregnancy rate

Timepoint

14 days after embryo transfer

Method of measurement β hCG ,14 days after embryo transfer**2****Description**

Abortion rate

Timepoint

every 2 months

Method of measurement β hCG and ultrasonography**Secondary outcomes****1****Description**

Quality of embryo

Timepoint

Embryo transfer

Method of measurement

Morfology

2**Description**

1,25(OH)2D3

Timepoint

Before ovum pick up

Method of measurement

Blood sampling

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

Intervention group:Tablet Ca-D BID

Category

Treatment - Drugs

2**Description**

Control Group:Tablet of Ca BID

Category

Treatment - Drugs

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

Infertility and recurrent pregnancy loss

Full name of responsible person

Dr Amir hasan Zarnani

Street address

Shariati-Yakhchal

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Avicenna research center

Full name of responsible person

Dr Akhondi Mohammad Mehdi

Street address

Yakhchal-Shariati

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Avicenna research center

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

Infertility and recurrent pregnancy loss center

Full name of responsible person

Dr Zafardoost Simin

Position

Obstetrics and Gynecologist-fellowship in infertility

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Biotechnologic and Fertility research center

Full name of responsible person

Amir Hasan Zarnani.PhD

Position

Imunology PhD

Other areas of specialty/work

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Infertility and biotechnologic Research Center

Full name of responsible person

Simin Zafardoost

Position

Obstetrics and Gynecologist-Fellowship in infertility

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