

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Role Of Vitamin D In Reproductive Success Following Intra Uterin Insemination In Polycystic Ovary Syndrome Patients

Protocol summary

Summary

This is a randomized clinical trial which has two groups: In the intervention group there are 40 women with Polycystic Ovary Syndrome who will get Vitamin D two months before IUI. In control group there are 40 women, with Polycystic Ovary Syndrome who will get placebo two months before IUI. Our placebo is identical to vitamin D ampoules in all regards. It is hence made using sesame oil, the base component in vitamin D ampoules; it, however, does not have any of the active ingredients of the very ampoule. Then patients will enter to COH-IUI and pregnancy rate in patients will be compared.

General information

Acronym

Role vitamin D in Reproductive success

IRCT registration information

IRCT registration number: **IRCT201104216246N1**

Registration date: **2011-09-04, 1390/06/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-09-04, 1390/06/13

Registrant information

Name

Mojgan Asadi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0037

Email address

asadim@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Endocrinology & Metabolism Research Center Tehran
University Of Medical Sciences

Expected recruitment start date

2011-09-06, 1390/06/15

Expected recruitment end date

2012-01-05, 1390/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role Of Vitamin D In Reproductive Success Following
Intra Uterin Insemination In Polycystic Ovary Syndrome
Patients

Public title

Role Of Vitamin D In Reproductive Success Following
Intra Uterin Insemination In Polycystic Ovary Syndrome
Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All Patients with polycystic Ovary
Syndrome who referred to infertility clinic, candidate for
IUI and Vitamin D Level Less than 100ng/ml. Exclusion
criteria: All Patients with other causes of infertility and
patients with Vitamin D Level more than 100ng/ml.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

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

Ethics Committee of Endocrinology& Metabolism
Research Center

Street address

5th Floor, Shariati Hospital, North Kargar
Ave, 1411413137 Tehran Iran

City

Tehran

Postal code

Approval date

2011-02-10, 1389/11/21

Ethics committee reference number

E-00112

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

After 14 days of sperm transfer

Method of measurement

B-hcG

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

At the time of fetal heart is seen

Method of measurement

vaginal sonography

Intervention groups

1

Description

Intervention group : muscular injection of Vitamin D
300000 unit

Category

Treatment - Drugs

2

Description

Control group: muscular injection of placebo (Our
placebo is made using sesame oil, the base component
in vitamin D ampoule)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's Hospital Infertility Clinic

Full name of responsible person

Mojgan Asadi

Street address

Women's hospital, Ostad Nejatollahi Shomally
Avenue, Karim Khan Zand bridge

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology& Metabolism Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Dr. Amini

Street address

5th Floor, Shariati Hospital, North Kargar Ave,
1411413137, Tehran, Iran

City

Tehran

Grant name

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

Yes

Title of funding source

Endocrinology& Metabolism Research Center, Tehran
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****Name of organization / entity**

Endocrinology& Metabolism Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Mojgan Asadi

Position

Assistant professor

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

5th Floor, Shariati Hospital, North Kargar Ave,
1411413137, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 8822 0037

Fax**Email**

asadim@tums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Endocrinology& Metabolism Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Mojgan Asadi

Position

Assistant professor

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

5th Floor, Shariati Hospital, North Kargar Ave,
1411413137, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 8822 0037

Fax**Email**

asadim@tums.ac.ir

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

Endocrinology& Metabolism Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Mojgan Asadi

Position

Assistant professor

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

5th Floor, Shariati Hospital, North Kargar Ave,
1411413137, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 8822 0037

Fax**Email**

asadi@tums.ac.ir

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