

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluating the effect of vitamin D treatment among patients with vitamin D deficiency on the outcome of IVF in poor responder IVF candidates; A clinical trial.

Protocol summary

Study aim

Determining and comparing the effect of vitamin D treatment in people with deficiency on the outcome of IVF in poor IVF women respondents in Akbarabadi Hospital

Design

A clinical trial with 2 intervention groups and 1 control group, with parallel groups was performed on 65 patients.

Settings and conduct

This study will be performed in Akbarabadi Women's Hospital in Tehran on mothers who are candidates for IVF-assisted reproductive therapy who have the necessary criteria. In this study, 2 intervention groups and 1 control group will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Maternal consent to perform diagnostic and laboratory procedures • Conscious consent to participate in this long-term study • Mother age between 20-40 years • According to the Poseidon criteria, the patient should be considered as a group 3 and 4 of Poor responder IVF mothers. Exclusion criteria: • Patient dissatisfaction with participation in the study • Existence of liver problems • Existence of cardiovascular problems • Endometriosis • Existence of kidney problems • Increase or decrease thyroid function • Hyperprolactinemia • BMI above 30 • BMI under 18

Intervention groups

Patients are classified into 3 groups: vitamin D deficiency (below 10 ng), inadequate vitamin D (between 11-30 ng), and patients with adequate vitamin D (above 30 ng). Patients with vitamin D deficiency and insufficient levels are treated with vitamin D. Vitamin D treatment is performed at 50,000 units per week, equivalent to 1250 micrograms of vitamin D for 6-8 weeks.

Main outcome variables

The results of the study are reported as the success rate

of IVF as the main goal and the pregnancy rate as the secondary goal.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210820052235N1**

Registration date: **2022-06-06, 1401/03/16**

Registration timing: **prospective**

Last update: **2022-06-06, 1401/03/16**

Update count: **0**

Registration date

2022-06-06, 1401/03/16

Registrant information

Name

Maryam Sadat Mirsharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5560 6034

Email address

dr_mirsharifi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the effect of vitamin D treatment among patients with vitamin D deficiency on the outcome of IVF in poor responder IVF candidates; A clinical trial.

Public title
The effect of vitamin D on the outcome of IVF therapy in women with poor response to IVF treatment.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Consent of mother for diagnostic and laboratory measurement
Obtaining an informed consent form to participate in the study
Age between 20-40
Patients must be among group 3 or 4 of poor responder patients to IVF treatment, based on Poseidon criteria.
Exclusion criteria:
Lack of consent for contributing in the study
Any level of liver failure
Cardiovascular diseases
Endometriosis
Chronic kidney disease
Thyroid dysfunction
Hyperprolactinemia
BMI over 30

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **65**

Randomization (investigator's opinion)
Not randomized

Randomization description

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
Ethics committee of Iran University of Medical Sciences
Street address
Hemmat EXP.

City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2022-01-30, 1400/11/10
Ethics committee reference number
IR.IUMS.FMD.REC.1400.600

Health conditions studied

1

Description of health condition studied

Female infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
The main result of the study is reported as IVF success rate
Timepoint
After childbirth
Method of measurement
Successful and failure rate of the pregnancy

2

Description
Pregnancy rate
Timepoint
16th weeks of pregnancy
Method of measurement
The number of pregnancies relative to the number of ovum transfer cycles

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Vitamin D deficient (Vitamin D level < 10 ng/dl). These patients will receive Pearl Vitamin D 50000 units per week for 6-8 weeks (Equal to 1250 micrograms weekly).
Category
Treatment - Drugs

2

Description

Control group: Sufficient vitamin D level (Vitamin D level > 30 ng/dl). These patients will receive Placebo just same as Pearl Vitamin D that would given to intervention groups per week for 6-8 weeks.

Category

Treatment - Drugs

3

Description

Intervention group: Vitamin D insufficient (Vitamin D level 10-30 ng/dl). These patients will receive Pearl Vitamin D 50000 units per week for 6-8 weeks (Equal to 1250 micrograms weekly).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Hospital

Full name of responsible person

Maryam Sadat Mirsharifi

Street address

Molawi st.

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Tehran

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Postal code

4351411687

Phone

+98 21 5560 6034

Email

dr_mirsharifi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Sadat Mirsharifi

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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

Iran University of Medical Sciences

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

Iran University of Medical Sciences

Full name of responsible person

Maryam Sadat Mirsharifi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data can be shared after deidentification.

When the data will become available and for how long

In 2024

To whom data/document is available

Researchers and GYN & OB Clinicians

Under which criteria data/document could be used

To make sure about the accuracy of the data and using them for research purposes.

From where data/document is obtainableBy sending an email to Dr. Maryam Sadat Mirsharifi:
dr_mirsharifi@yahoo.com**What processes are involved for a request to access data/document**

Within 72 hours from the request, we will respond to the request

Comments