

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Study of the effect of 1.25 Dihydroxy-vitamin D3 on the Th17/Treg (Cd4, FoxP3) ratio in the women with recurrent spontaneous abortion with vitamin D3 deficiency candidate for lymphocyte therapy

Protocol summary

Summary

Study target: Study of the effect of 1.25 Dihydroxy-vitamin D3 in the women with recurrent spontaneous (RSA) abortion with immunology reasons. Study design: randomized, double blind, controled with placebo. Inclusion criteria: 1) women with RSA in age 20-45 years with possibility of immunology reasons candidate for lymphocyte therapy; 2) the women with RSA who have serum levels of vitamin D3 less than or equal 100 nmol/l; 3) having a regular menstrual cycle. Exclusion criteria: 1) having an irrigrular menstrual cycle 2) women who have consumed vitamin D3 in three months ago. Sample size: 44 persons. Intervention: injection of vitamin D3 or placebo. Time of injection: with the onset of lymphocyte therapy. The primary outcome: increasing Treg and decreasing TH17.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201258820N1**
Registration date: **2012-03-12, 1390/12/22**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-03-12, 1390/12/22

Registrant information

Name

Mtra Rafiee

Name of organization / entity

Isfahan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan university of medical sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of 1.25 Dihydroxy-vitamin D3 on the Th17/Treg (Cd4, FoxP3) ratio in the women with recurrent spontaneous abortion with vitamin D3 deficiency candidate for lymphocyte therapy

Public title

Therapeutic effects of vitamin D3 in women with recurrent spontaneous abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) women with RSA in age 20-45 years with possibility of immunology reasons candidate for lymphocyte therapy; 2) the women with RSA who have serum levels of vitamin D3 less than or equal 100 nmol/l; 3) having a regular menstrual cycle. Exclusion criteria: 1) having an irrigrular menstrual cycle 2) women who have consumed vitamin D3 in three months ago.

Age
From **20 years** old to **45 years** old
Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **44**

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
Isfahan university of medical sciences

Street address
Daneshgah avenue, Azadi square

City
Isfahan

Postal code
8174673461

Approval date
2012-02-25, 1390/12/06

Ethics committee reference number
190057

Health conditions studied

1

Description of health condition studied
recurrent spontaneous abortion with immunology reasons

ICD-10 code
O00-O08

ICD-10 code description
pregnancy with abortive outcome

Primary outcomes

1

Description

Treg
Timepoint
before intervention and 3 months of intervention
Method of measurement
with flow cytometry by detect CD4 and FoxP3 markers

2

Description
TH17

Timepoint
before intervention 3 months of intervention

Method of measurement
with flow cytometry by detect CD4 and IL17 markers

3

Description
TH17 to Treg ratio

Timepoint
before intervention and 3 months of intervention

Method of measurement
with dividing of TH17 to Treg

4

Description
The levels of vitamin D

Timepoint
before and after intervention

Method of measurement
Elisa

Secondary outcomes

1

Description
pregnancy outcome

Timepoint
from 3 months after the end of treatment

Method of measurement
infant birth

Intervention groups

1

Description
Intervention group: injection of vitamin D3, 300000 IU, one injection

Category
Treatment - Drugs

2

Description
Control group: injection placebo containing solvent material of vitamin D3, one injection

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Novin laboratory

Full name of responsible person

Dr Abase Rezaie

Street address

Amadegah avenue, Char bagh abassi street

City

Isfahan

2

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Mitra Rafiee

Street address

in front of Aseman hotel, pole felezi

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan university of medical sciences

Full name of responsible person

Vice chancellor for research and technology, Dr

Peyman Adibi

Street address

Isfahan university of medical sciences building NO.4,

Daneshgah avenue, Azadi square

City

Isfahan

Grant name

3-124400

Grant code / Reference number

10506

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

Yes

Title of funding source

Isfahan 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

Isfahan university of medical sciences

Full name of responsible person

Mitra Rafiee

Position

MSC Student

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

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PhD

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Person responsible for updating data

Contact

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