

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 1444 7331

##### Email address

gharagozlo@med.mui.ac.ir

##### 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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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr Abase Rezaei

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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*