

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessment of Tacrolimus Efficacy in Patients with Recurrent Pregnancy Loss.

#### Protocol summary

##### Study aim

Assessment of Tacrolimus Efficacy in Patients with Recurrent Pregnancy Loss.

##### Design

After obtaining informed consent, patients will be enrolled in the study based on the inclusion and exclusion criteria. 100 patients, from the day of a positive pregnancy test, oral tacrolimus at a dose of 0.5 mg twice daily (bd) will be prescribed and continued until the 10th week of pregnancy. Patients will be followed up until at least the 37th week of gestation and delivery.

##### Settings and conduct

The clinic of Dr. Soheila Arefi and the Avicenna Infertility Center in Tehran, Iran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : 1: Women aged between 20 and 39 years . 2: Patients who presented for treatment of recurrent miscarriage (three or more miscarriages before 12 weeks of gestation, with documented fetal heart rate [FHR]) . 3: Patients with unexplained infertility despite evaluation, including assessment of ovulatory function, tubal patency, uterine anatomical abnormalities, cervical factors, and sperm quality and quantity . 4: Patients who are able to continue regular follow-up visits during the study period . Exclusion criteria : 1: Patients using immunosuppressive medications for infertility treatment, such as azathioprine, mizoribine, mycophenolate mofetil . 2: Chronic endometritis diagnosed by endometrial biopsy. 3: Uterine anomalies, uterine fibroids, endometrial polyps, or intrauterine adhesions . 4: Active infections including HIV, hepatitis B, hepatitis C, or other active viral diseases .

##### Intervention groups

Patients with Recurrent Pregnancy Loss

##### Main outcome variables

Outcome Assessment: To confirm or rule out pregnancy, serum  $\beta$ -hCG levels will be measured. If serum  $\beta$ -hCG is positive, patients will be followed up until the 37th week of gestation and the end of pregnancy to assess for live

birth.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250527065938N1**

Registration date: **2025-06-20, 1404/03/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-06-20, 1404/03/30**

Update count: **0**

##### Registration date

2025-06-20, 1404/03/30

##### Registrant information

##### Name

Somayyeh Shaikh alian zafarghandi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 612 0791

##### Email address

mahyar.fasihi80@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-06-06, 1404/03/16

##### Expected recruitment end date

2026-06-06, 1405/03/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Assessment of Tacrolimus Efficacy in Patients with Recurrent Pregnancy Loss.

### Public title

Assessment of Tacrolimus Efficacy in Patients with Recurrent Pregnancy Loss.

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Women aged between 20 and 39 years. Patients who presented for treatment of recurrent miscarriage (three or more miscarriages before 12 weeks of gestation, with documented fetal heart rate [FHR]). Patients with unexplained infertility despite evaluation, including assessment of ovulatory function, tubal patency, uterine anatomical abnormalities, cervical factors, and sperm quality and quantity. Patients who are able to continue regular follow-up visits during the study period.

#### Exclusion criteria:

Patients using immunosuppressive medications for infertility treatment, such as azathioprine, mizoribine, mycophenolate mofetil, cyclophosphamide, sirolimus, everolimus, cyclosporine, basiliximab, etanercept, golimumab, cantuzumab, tocilizumab, conatumumab, corticosteroids, or intravenous immunoglobulin (IVIG). Chronic endometritis diagnosed by endometrial biopsy. Uterine anomalies, uterine fibroids, endometrial polyps, or intrauterine adhesions. Active infections including HIV, hepatitis B, hepatitis C, or other active viral diseases.

### Age

From **20 years** old to **39 years** old

### Gender

Female

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

N/A

### 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

Avicenna Research Institute, Iranian Academic Center for Education, Culture and Research (ACECR)

#### Street address

Shahid Beheshti University, Rashideddin Fazlollah Street, Yemen Street, Chamran Expressway (North to South), Tehran, Iran.

#### City

Tehran

#### Province

Tehran

#### Postal code

1936773493

### Approval date

2025-05-25, 1404/03/04

### Ethics committee reference number

IR.ACECR.AVICENNA.REC.1404.003

## Health conditions studied

## 1

### Description of health condition studied

Recurrent Pregnancy Loss .

### ICD-10 code

Tacrolimus

### ICD-10 code description

Tacrolimus Efficacy in Patients with Recurrent Pregnancy Loss .

## Primary outcomes

## 1

### Description

Live Births .

### Timepoint

Evaluation of the Effect of Tacrolimus on Recurrent Pregnancy Loss Based on the Number of Live Births 18 month evaluation.

### Method of measurement

Evaluation of the Effect of Tacrolimus on Recurrent Pregnancy Loss Based on the Number of Live Births.

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group .Tacrolimus prescription

### Category

Treatment - Drugs

2

**Description**

Control group: Follow pregnant women without take Tacrolimus.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Dr. Soheila Arefi's Clinic

**Full name of responsible person**

Dr. Soheila Arefi

**Street address**

No. 28, Kohestan Street, Ketab Square, Saadat Abad, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1669743789

**Phone**

+98 912 612 0791

**Email**

mahyarfasihi@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

No. 971941913114, Yakhchal Street, Dr. Shariati Street, Tehran, Iran.

**Full name of responsible person**

Avicenna Infertility and Recurrent Abortion Specialty Center, Tehran, Iran.

**Street address**

No. 97 Postal Code: 1941913114, Avicenna Infertility Center, Dr. Shariati Street, Yakhchal Street, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1941913114

**Phone**

+98 21 23519

**Email**

info@avicennaclinic.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

No. 971941913114, Yakhchal Street, Dr. Shariati Street, Tehran, Iran.

**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**

Avicenna Infertility Center Dr. Shariati Street, Yakhchal Street, Tehran, Iran.

**Full name of responsible person**

Somayyeh Shaikhalian Zafarghandi

**Position**

Infertility fellowship student

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

No. 6, Unit 10, 4th Floor, Eftekhariyan Street, Azizi Alley, Pasdaran, Heravi Square, Mobarak Abad 3-way, Tehran, Iran.

**City**

Tehran

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1669743789

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mahyar.fasihi80@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Avicenna Infertility Research Center

**Full name of responsible person**

Somayyeh Shaikhalian Zafarghandi

**Position**

Infertility fellow student

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Avicenna Infertility Research Center  
**Full name of responsible person**  
Somayyeh Shaikhalian Zafarghandi  
**Position**  
Infertility fellow Student  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
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No. 97, 1941913114. Yakhchal Street . Dr. Shariati  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

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

### Study Protocol

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

### Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

### Analytic Code

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

### Data Dictionary

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