

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 β -hCG levels will be measured. If serum β -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

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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

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Person responsible for updating data

Contact

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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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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