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 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
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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
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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 AlleyPasdaran, Heravi Square, Mobarak Abad 3-way,Tehran,Iran.
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Avicenna Infertility Research Center
Full name of responsible person
Somayyeh Shaikhaluan Zafatghandi
Position
Infertility fellow student
Latest degree
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Other areas of specialty/work
Gynecology and Obstetrics
Street address
No. 6, Unit 10, 4th Floor, Azizi Alley, Eftekhariyan Street, Heravi Square, Mobarak Abad 3-way, Tehran, Iran.
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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 felloow Student

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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City
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Tehran

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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