# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**
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**Province**
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1669743789
**Phone**
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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.
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**Province**
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**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**
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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

**Street address**
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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