

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effects of Tacrolimus on pregnancy outcome in women with recurrent implantation failure (RIF) associated with immunologic factors: clinical trial

Protocol summary

Study aim

The effects of Tacrolimus on pregnancy outcome in women with recurrent implantation failure (RIF) associated with immunologic factors: clinical trial

Design

Clinical trial with control group, with parallel group, double blind, randomized, phase 2 on 50 patients. A table of random numbers will be used for randomization.

Settings and conduct

This study is a clinical trial; First, written and informed consent will be received from people with RIF (50 people) who have a history of repeated implantation failure 3 times and have referred to Al-Zahra Infertility Center and Azerbaijan Infertility Center in Tabriz, and constitute our target population in this project.

Participants/Inclusion and exclusion criteria

In conducting this study, our important criteria for patients to enter the study include the following: Since the genetics and race of each person are effective in the effectiveness of the drug, our patients will be selected only from Azari-speaking people. Patients who do not have any type of immunotherapy in their medical history will be included in the study. Our criteria for withdrawing patients from the study also include the following: Patients under 18 years old and over 41 years old Patients who themselves or their spouses have abnormal karyotypes or genetic and chromosomal disorders. Patients with coagulation problems. Patients who have an underlying chronic disease and have to take special drugs. Patients with intrauterine anomalies.

Intervention groups

1 to 2 mg of tacrolimus drug is prescribed orally 2 days before the transfer and 14 days after the transfer, taking into account the activity of the immune system of the patients. We will compare the control group that did not receive any treatment (received routine treatments but did not receive tacrolimus).

Main outcome variables

Pregnancy rate

General information

Reason for update

Acronym

TPORIF

IRCT registration information

IRCT registration number: **IRCT20160422027520N22**

Registration date: **2023-02-20, 1401/12/01**

Registration timing: **prospective**

Last update: **2023-02-20, 1401/12/01**

Update count: **0**

Registration date

2023-02-20, 1401/12/01

Registrant information

Name

Mehdi Yousefi

Name of organization / entity

Department of Immunology, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 4665

Email address

yousefime@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-01, 1401/12/10

Expected recruitment end date

2023-12-31, 1402/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Tacrolimus on pregnancy outcome in women with recurrent implantation failure (RIF) associated with immunologic factors: clinical trial

Public title

Investigating the effect of tacrolimus on fertility in women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Disturbed ratio (Th1/Th2) Patients who have experienced at least 3 consecutive implantation failures will be included in our study. Patients who do not have any type of immunotherapy in their medical history will be included in the study.

Exclusion criteria:

Patients under 18 years old and over 41 years old Patients who themselves or their spouses have abnormal karyotypes or genetic and chromosomal disorders. Patients with coagulation problems. Patients who have an underlying chronic disease and have to take special drugs. Patients whose HIV, HCV or HBV test results are positive. Patients who have a history of asthma and allergy to certain drugs. Patients with intrauterine anomalies.

Age

From **18 years** old to **41 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of random allocation will be with the help of a table of random numbers, and patients will be placed in one of two study groups based on the order of entry into the study and the results of random number calculations.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants and the person who analyzed the results were blinded in this study. Participants were aware of the study before being randomized and informed consent was obtained from them. It should be noted that the person analyzing the results had no other role in this

study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences , Daneshghah st, Tabriz,

City

Tabriz

Province

East Azarbaijan

Postal code

6446-14155

Approval date

2023-01-23, 1401/11/03

Ethics committee reference number

IR.TBZMED.REC.1401.945

Health conditions studied**1****Description of health condition studied**

Recurrent implantation failure

ICD-10 code

N98.9

ICD-10 code description

Complication associated with artificial fertilization, unspecified

Primary outcomes**1****Description**

Pregnancy rate

Timepoint

After positive beta-hCG test, clinical pregnancy was evaluated at 5-6 week

Method of measurement

Examining the formation of gestational sac using Sonography method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: According to the protocol, 1 to 2 mg of tacrolimus drug is administered orally to the study subjects daily, taking into account the level of immune system activity of the patients 2 days before the transfer and 14 days after the transfer.

Category

Treatment - Drugs

2

Description

Control group: receive no intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility center at Alzahra Hospital

Full name of responsible person

Dr. Mehdi Yousefi

Street address

South Artesh Street, Alzahra Medical Education Center

City

Tabriz

Province

East Azarbaijan

Postal code

6446-14155

Phone

+98 41 3327 3000

Email

mehdi_yusefi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

Street address

Tabriz University of Medical Sciences , Daneshghah st, Tabriz,

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 4665

Email

mehdi_yusefi@yahoo.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Yousefi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

Street address

Tabriz University of Medical Sciences , Daneshghah st, Tabriz,

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 4665

Email

mehdi_yusefi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Yousefi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

Street address

Tabriz University of Medical Sciences , Daneshgah
st, Tabriz,

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3336 4665

Fax

+98 41 3336 4665

Email

mehdi_yusefi@yahoo.com

Web page address

st, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5414846649

Phone

+98 41 3336 4665

Email

amir.valizadeh67@gmail.com

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

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Yousefi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

Street address

Tabriz University of Medical Sciences , Daneshgah