

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of IVIg on Pregnancy Rate of Patient with Recurrent Implantation Failure with Immunological Causes

Protocol summary

Summary

Over the decades assisted reproductive technologies and in vitro fertilization (IVF) help infertile couples to conceive, however the implantation rate is one of the limiting factors in assisted reproductive techniques. The aim of our study is to select patients with repeated implantation failure (RIF) on the basis of immunological disorders and their treatment with IVIG. The study included 40 patients with repeated implantation failure ranging from 18 to 41 years and IVIG at a dose of 400 mg per kilogram of body weight will be used to treat patients. RIF patients will be selected from September 95 to June 96 in Alzahra Hospital Fertility Center and one or two days before the embryo transfer will receive one dose IVIG. Inclusion criteria included the failure of IVF at least 3 times and immunological disorders. Exclusion criteria included genetic and chromosomal disorders and Immunotherapy history. Finally, after embryo transfer IVF success rates will evaluate by β HCG and ultrasound. Moreover, patients immunological parameters will be evaluated before and after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080527520N3**

Registration date: **2016-08-24, 1395/06/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-24, 1395/06/03

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

Drug Applied Research Center, Tabriz University of
Medical Sciences, Tabriz, Iran

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of IVIg on Pregnancy Rate of Patient with Recurrent
Implantation Failure with Immunological Causes

Public title

IVIg and treatment of recurrent implantation failure (RIF)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who experienced at least two
implantation failure; patients with Azeri origin; Patients
who did not have any type of immunotherapy in his
medical history. Exclusion criteria: Patients below 18
years and above 41 years; Patients with abnormal
karyotype or chromosomal disorders; patients who have

bleeding problems; Patients who have chronic disorders such as diabetes; Patients who have HIV, HCV or HBV positive tests; Patients who have a history of asthma and allergies to certain drugs; patients who have uterus anomalies.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Drug Applied Research Center

Street address

Tabriz University of Medical Sciencesabriz,
Daneshghah st, Tabriz, Iran

City

Tabriz

Postal code**Approval date**

2016-07-04, 1395/04/14

Ethics committee reference number

IR.TBZMED.REC.1395.315

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**

Embryo Implantation

Timepoint

2 month after intervention

Method of measurement

Laboratory tests and ultrasound

Secondary outcomes**1****Description**

Changes in immune cells

Timepoint

2 month after intervention

Method of measurement

Flow cytometry, ELISA, RT-PCR

Intervention groups**1****Description**

1 or 2 days before embryo transfer 400 mg per kilogram
of IVIG will be administered intravenously.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr Majidi infertility center of Tabriz Alzahra Hospital

Full name of responsible person

Mehdi Yousefi

Street address

Department of Immunology, Tabriz University of
Medical Scaences, Tabriz, Iran

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz university of medical sciences

Full name of responsible person

Mohammad Reza Rashidi

Street address

Tabriz University of Medical Scieences

City

Tabriz

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Yousefi

Position

PhD of Medical Immunology

Other areas of specialty/work**Street address**Department of Immunology, School of Medicine,
Tabriz University of Medical Sciences, Tabriz, Iran**City**

Tabriz

Postal code**Phone**

+98 413364665

Fax**Email**

mehdi_yusefi@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz university of medical sciences

Full name of responsible person

Mehdi Yousefi

Position

PhD of Immunology

Other areas of specialty/work**Street address**Department of Immunology, Tabriz University of
Medical Sciences,**City**

Tabriz

Postal code**Phone**

+98 413364665

Fax**Email**

mehdi_yusefi@yahoo.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Majid Ahmadi

Position

PhD of Immunology

Other areas of specialty/work**Street address**Department of Immunology, Faculty of Medicine,
Tabriz, Iran**City**

Tabriz

Postal code**Phone**

+98 413364665

Fax**Email**

m.ahmadi6892@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty