

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Effect of IVIg on Pregnancy Rate of Patient with recurrent pregnancy loss with Immunological Causes

Protocol summary

Summary

This study designed to identify the immunological causes of recurrent miscarriage and using IVIG for treatment of these patients. In this study patients with recurrent spontaneous abortion in terms of immunological problems investigated and 40 patients with cellular immunity abnormalities will be selected. The patients ranging from 20 to 41 years and IVIG will be used at a dose of 400 mg per kilogram of body weight to treat patients. Patients will be selected from September 95 to June 96 in Al-Zahra Infertility Center Hospital in Tabriz and as soon as the pregnancy will receive a dose of IVIG therapy and then every 4 weeks during pregnancy will receive IVIG treatment. At the end of 32 weeks the last dose of the IVIG will be injected into the patient. The main inclusion criteria included at least three times abortion and cellular immune system problems. Exclusion criteria include anatomical, genetic and chromosomal abnormalities and immunotherapy history. At the end of treatment, the pregnancy success rate and changes to the immune system will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050127520N2**

Registration date: **2016-09-02, 1395/06/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-02, 1395/06/12

Registrant information

Name

Mehdi Yousefi

Name of organization / entity

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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

2016-12-21, 1395/10/01

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
pregnancy loss with Immunological Causes

Public title

IVIg and treatment of recurrent spontaneous abortion
(RSA)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who experienced at least three
miscarriage; 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**

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- daneshgah st- tabriz university of medical sciences

City

Tabriz

Postal code

7386-51656

Approval date

2016-07-04, 1395/04/14

Ethics committee reference number

IR.TBZMED.REC.1395.316

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

Recurrent aburtion

ICD-10 code

O03

ICD-10 code description

Spontaneous abortion

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

Pregnancy rate

Timepoint

After treatment

Method of measurement

Live birth

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

Immune cells modification

Timepoint

After treatment

Method of measurement

Flow cytometry, ELISA, RT-PCR

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

IVIG 400 mg per kg of body weight once every four weeks until week 32 of pregnancy

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**City**

Tabriz

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

Tabriz university of medica; sciences

Full name of responsible person

Mohammad Reza Rashidi

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City

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor**

organization/entity?

Yes

Title of funding source

Tabriz university of medica; 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**

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Position

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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