

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Low-Dose Intravenous Immunoglobulin decrease rate of Immunologic Abortion; a clinical trial

Protocol summary

Summary

Abortion is a common and inevitable event and also major cause of anxiety for a couple while trying pregnancy. There is no certain therapeutic regimen to overcome abortion complete. Here we investigated the success rate of low-dose IVIG in comparison with aspirin usage in the treatment of recurrent miscarriage. This clinical trial study consisted of 50 women referred to Ghaem Hospital, Mashhad University of Medical Sciences, Mashhad, Iran. The cases were randomly divided into two groups of 25 individuals. Aspirin (80 mg) was administered daily to the control group, while in the study group 5 g IVIG was administered in 8 doses: once before pregnancy and then monthly for up to 32 weeks of gestation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021220993N2**

Registration date: **2015-03-11, 1393/12/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-03-11, 1393/12/20

Registrant information

Name

Majid Jafari

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2770

Email address

jafarim912@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of research in Mashhad University of Medical Sciences

Expected recruitment start date

2007-03-20, 1385/12/29

Expected recruitment end date

2009-03-20, 1387/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Low-Dose Intravenous Immunoglobulin decrease rate of Immunologic Abortion; a clinical trial

Public title

Intravenous Immunoglobulin decrease rate of Immunologic Abortion

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: women with at least two abortions that had taken place naturally or with assisted reproductive techniques (ART) and who had at least one positive immunologic test for anti-cardiolipin; anti-phospholipid antibodies; anti-thyroid antibody; anti-nuclear antibody; Anti-sperm antibody. Exclusion criteria: anatomical problems; infections; hormonal factors contributing to recurrent abortion and parental factors were excluded.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Regional ethics committee in Mashhad University of Medical Sciences

Street address

Mashhad, Daneshgah Street, Ghoreishi Building, 2nd floor, Ethics committee office

City

Mashhad

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

84123

Health conditions studied

1

Description of health condition studied

Abortion

ICD-10 code

Z35.1

ICD-10 code description

Supervision of pregnancy with history of abortive outcome

Primary outcomes

1

Description

neonate

Timepoint

9 month

Method of measurement

Delivery

Secondary outcomes

1

Description

Abortion

Timepoint

Each time after intervention

Method of measurement

exposing symptoms of abortion

2

Description

premature birth

Timepoint

Each time after intervention

Method of measurement

exposing symptoms of premature birth

Intervention groups

1

Description

Aspirin (80 mg) was administered daily to the control group

Category

Treatment - Drugs

2

Description

the study group 5 g IVIG was initiated within 2 weeks prior to attempted conception. After conception occurred, IVIG was given every 4 weeks for up to 32 weeks of gestation. IVIG was administered in hospital through vein perfusion during a 3-6 hour period and clinical signs and symptoms were controlled under the supervision of a clinical allergy and immunology fellowship resident."

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Majid jafari fellowship of allergy and clinical immunology

Street address

allergy and clinical immunology ward, Ghaem Hospital

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research in Mashhad University of Medical Sciences

Full name of responsible person

Dr. Saieed Eslami

Street address

Research Managment, Ghoreieshi Building, daneshgah Street, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of research in Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

majid jafari

Position

fellowship

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Person responsible for updating data

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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