

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of adding intravenous immunoglobulin to heparin and aspirin regiment for prevention of reccurent abortion

Protocol summary

Summary

it is A double-blind, randomized, study is doing to evaluate the efficacy of i.v. immunoglobulin in the prevention of reccurent abortion in patient with reccurent abortion in emam khomini hospital in sari 2012. The study was approved by the Local Ethics Committee. inclusion criteria: pregnant women with reccurent abortion (was defined as two or more consecutive fetal losses before the 20th gestational week). exclusion criteria: other cause for abortion such as structural and anatomical disorder; Abnormal result of chromosomal analysis of the couple; using anti coagulant in pregnancy; aspirin sensivity; hypertention; peptic ulcer. We examined 68 women with recurrent abortion. The subjects were randomly assigned to treatment with low molecular weight heparin 40 mg daily until 24th week plus low-dose aspirin 80mg daily until 37th week and in other group IVIG 200mg/kg until 24th week with LMWH and aspirin as the same regimn. Both therapies were started when the women were pregnant as documented by a positive urine test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012081210568N1**

Registration date: **2013-03-16, 1391/12/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-16, 1391/12/26

Registrant information

Name

Zinab Nazari

Name of organization / entity

University of Medical Sciences Mazandaran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2011-07-01, 1390/04/10

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of adding intravenous immunoglobulin to heparin and aspirin regiment for prevention of reccurent abortion

Public title

Effect of adding intravenous immunoglobulin to heparin and aspirin regiment for prevention of reccurent abortion

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: pregnant women with reccurent abortion (was defined as two or more consecutive fetal losses before the 20th gestational week). exclusion criteria: other cause for abortion such as structural and anatomical disorder; Abnormal result of chromosomal analysis of the couple; using anti coagulant in pregnancy; aspirin sensivity; hypertention; peptic ulcer.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 68

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**

Mazandaran University of Medical Sciences

Street address

Moallem Square

City

Sari

Postal code

98

Approval date

2011-05-22, 1390/03/01

Ethics committee reference number

90-22

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

Recurrent Abortion

ICD-10 code

Pregnancy,

ICD-10 code description

Pregnancy with abortive outcome

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

recurrent abortion

Timepoint

4th month after intervention

Method of measurement

physical examination

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

continue of pregnancy

Timepoint

when pregnancy terminat

Method of measurement

physical exam

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

in control group treatment is Low Molecular Weight Heparin(noxaparin) 40 mg daily sub cotaneus for 24 weeks And Aspirin 80 mg daily for 37 weeks.

Category

Treatment - Drugs

2**Description**

case group treat with IVIG 200 mg/kg mounthly for 24 weeks and Low Molecular Weight Heparin(noxaparin) 40 mg daily sub cotaneus for 24 weeks And Aspirin 80 mg daily for 37 weeks.

Category

Treatment - Drugs

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

Emam Khomeini Hospital

Full name of responsible person

Dr Zinab Nazari

Street address

Emam khomeini Hospital- Razi Street

City

Sari

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

Mazandaran University of Medical Sciences

Full name of responsible person

dr zinab nazari

Street address

Emam khomeini Hospital
City
 Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Mazandaran 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
 Mazandaran University of Medical Sciences
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Position
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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