Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A randomized controlled trial of prednisolone for women with idiopathic recurrent miscarriage and raised levels of Peripheral natural killer cells .

Protocol summary

Summary

We propose a randomized, double blind; placebo controlled clinical trial of prednisolone for woman with idiopathic recurrent miscarriage and raised levels of Natural Killer cells in the peripheral blood. All patients who fit the inclusion criteria: age 20-40 years old; history of more than 2 consecutive miscarriage with no cause found; CD 56 more than 12 or CD 16/56 more than 8 and no contraindication to prednisolone therapy, will be allow to enter the study. One hundred women with high level of peripheral Natural Killer cells will be randomized to either prednisolone or placebo groups. Follow up by checking CD56 and CD16/56 included 2 months before and after prednisolone or placebo therapy and at 8, 12 and 20 weeks of gestational age. The primary aim is to investigate whether prednisolone therapy before and during the pregnancy is able to improve live birth rates in patients with idiopathic recurrent miscarriage and decrease Natural Killer cells in peripheral blood. Secondary out comes include conception rate, still births, pregnancy complications, gestational age of delivery and side effects of prednisolone.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110915342N1**
Registration date: **2014-05-12, 1393/02/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-12, 1393/02/22

Registrant information

Name

Rashin Zargham

Name of organization / entity

Jahad Research Institute of Avicenna

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Avicenna Infertility and Recurrent Abortion Center

Expected recruitment start date

2013-11-21, 1392/08/30

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized controlled trial of prednisolone for women with idiopathic recurrent miscarriage and raised levels of Peripheral natural killer cells .

Public title

The effect of Prednisolone in reducing of recurrent abortion

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: female gender; being a case of idiopathic abortion; in flow cytometry of peripheral blood, CD56 more than 12 or CD 16/56 more than 8. Exclusion criteria: age less than 20 or more than 40 years old; having less than 2 abortions; history of abortion more

than 20w of gestational age; uterine disorder; chromosomal disorder in couples; antiphospholipid syndrome; contraindication of corticosteroid; abnormal thyroid function test result.

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Avicenna Research Institute Ethical Committee

Street address
Avicenna Research Institute, Evin

City
Tehran

Postal code
117719615

Approval date
2013-10-22, 1392/07/30

Ethics committee reference number
92020

Health conditions studied

1

Description of health condition studied
Idiopathic Recurrent Abortion

ICD-10 code
O03

ICD-10 code description
Miscarriage

Primary outcomes

1

Description
Abortion

Timepoint
12th and 20th weeks of gestation

Method of measurement
Patients file

2

Description
Live birth

Timepoint
After Birth

Method of measurement
Patient file

Secondary outcomes

1

Description
Peripheral Natural Killer Cell

Timepoint
Before intervention, 2 months after intervention, 8th, 12th, 20th weeks of gestation

Method of measurement
Flow cytometry

2

Description
Chemical pregnancy

Timepoint
1 week after retardation of mens

Method of measurement
Positive beta-hcg test

3

Description
Pre eclampsia

Timepoint
After 20th week of gestation

Method of measurement
Blood pressure measuring

4

Description
Drug Complications

Timepoint
After Treatment

Method of measurement
Patients files

5

Description
Gestational Diabetes

Timepoint
After 20th week of gestation
Method of measurement
FBS, GCT, GTT

6

Description
IUGR
Timepoint
After 28th week of gestation
Method of measurement
Obstetrical ultrasound scan

7

Description
Clinical Pregnancy
Timepoint
After 5-6 th week of gestation
Method of measurement
Obstetrical Ultra Sound Scan

8

Description
Ongoing Pregnancy
Timepoint
After 7th week
Method of measurement
Obstetrical Ultrasound Scan

9

Description
Gestational age at delivery
Timepoint
After 24th week of gestation
Method of measurement
Patient file

10

Description
Feotal Abnormality
Timepoint
At 20th weeks gestation
Method of measurement
Anomaly Ultrasound Scan

Intervention groups

1

Description
Case group are treated with prednisolone with this protocol: prednisolone 2 months before taking action to pregnancy; first week 20 mg daily; second week 15 mg daily ; third to seventh week 10 mg daily ; eighth week 5 mg daily.Then recheck NK-cell density , if there is suitable response, taking action to pregnancy will be allowed .After positive pregnancy test ,restarting prednisolone or placebo with this protocol:10mg daily until 14th week of gestational age ,when the dose will be tapered off and stopped. In addition, both of groups equally are treated with empirical treatment which have been effective in past studies of idiopathic recurrent abortion, including : ASA-FA5mg-vit B6.
Category
Treatment - Drugs

2

Description
Control group with placebo before and during pregnancy ;with this protocol: placebo 2 months before taking action to pregnancy; first week 20 mg daily; second week 15 mg daily ; third to seventh week 10 mg daily ; eighth week 5 mg daily.Then recheck NK-cell density , if there is suitable response, taking action to pregnancy will be allowed .After positive pregnancy test ,restarting placebo with this protocol:10mg daily until 14th week of gestational age ,when the dose will be tapered off and stopped. In addition, both of groups equally are treated with empirical treatment which have been effective in past studies of idiopathic recurrent abortion, including : ASA-FA5mg-vit B6.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Avicenna Infertility and Recurrent Abortion Center
Full name of responsible person
Dr. Rashin Zargham
Street address
No. 97, Yakhchal Avenue, Shariati Street, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Avicenna Research Institute
Full name of responsible person
Dr. Mohammad Mehdi Akhoondi
Street address
No 97, Yakhchal Avenue, Shariati Street, Tehran, Iran
City
Tehran
Grant name
113641
Grant code / Reference number
92-020
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Avicenna Research Institute

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

Avicenna Infertility and Recurrent Aborsion Center

Full name of responsible person

Dr Rashin Zargham

Position

Gynecologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Avicenna Infertility and Recurrent Aborsion Center

Full name of responsible person

Dr. Fatemeh Razzaghi, Dr.Saeed Zarei, Dr. Rashin zargham

Position

Gynecologist

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Person responsible for updating data

Contact

Name of organization / entity

Avicenna Infertility Center

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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