

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of metformine on the uteroplacental circulation in comparison with Aspirin in pregnant women with poly cystic ovary syndrome

Protocol summary

Summary

The purpose of this randomized, single-blind clinical trial was to determine and compare uteroplacental circulation and obstetrics complications in pregnant PCOS women treated with Aspirin or Metformine with control group. 105 patients were enrolled in the study after obtaining written consent and assessing uterine artery PI with doppler ultrasonography at 12th week of gestational age. The patients were assigned into three groups of 35 patients each using block randomization method to receive either Aspirin, 80 mg tablets daily Metformine, 2000 mg tablets, daily, or no intervention till the end of pregnancy. Uterine artery PI was assessed for the patients at 20th gestational week and they were followed until the end of pregnancy. Uterine artery PI, obstetrics complications such as preeclampsia, IUGR, GDM, and preterm Labor were assessed and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812123485N1**

Registration date: **2010-04-06, 1389/01/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-06, 1389/01/17

Registrant information

Name

Forozan Milani

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran university of medical science

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2009-09-21, 1388/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of metformine on the uteroplacental circulation in comparison with Aspirin in pregnant women with poly cystic ovary syndrome

Public title

The effect of metformine on the uteroplacental circulation in comparison with Aspirin in pregnant women with poly cystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: PCOS diagnosis before pregnancy was based on the presence of poly cystic ovaries verified by ultrasonography and oligomenorea (length of menstrual cycle more than 35 days or hirsutism, gestational age 5-12 weeks, single live fetus, pregnant women between 18-40years and Exclusion criteria: Inability to follow up

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran University of Medical Sciences

Street address

Shariati Hospital, North Karegar Ave.

City

Tehran

Postal code**Approval date**

2009-02-16, 1387/11/28

Ethics committee reference number

E-0072

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

Uteroplacental circulation and complication of pregnancy

ICD-10 code

E28.2

ICD-10 code description

Pcos (poly cystic ovary syndrome)

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

Uteroplacental circulation

Timepoint

At 12th week of gestational age (before intervention) and 8 weeks after intervention

Method of measurement

Uterine Artery Doppler Ultrasound

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

Preterm labour

Timepoint

After Delivery

Method of measurement

Termination of pregnancy before 37th gestational age

2**Description**

Preeclampsia

Timepoint

Monthly routine control of pregnancy

Method of measurement

Evaluation of BP and urine protein exam

3**Description**

Rate of Gestational Diabet

Timepoint

at 24-28 weeks of pregnancy or 12-16 weeks after intervention

Method of measurement

GTT

4**Description**

Rate of IUGR

Timepoint

After Delivery

Method of measurement

weight below the 10th percentile for gestational age after Delivery

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

Metformine, oral Tab, 2000 mg Daily until delivery

Category

Treatment - Drugs

2**Description**

Aspirin, oral Tab, 80 mg daily until delivery

Category

Treatment - Drugs

3**Description**

no treatment until delivery

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ashraf Jamal
Street address
Shariati Hospital, North Kargar Ave., Tehran
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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

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Person responsible for updating data

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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