

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 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: **IRCT201011295272N1**
Registration date: **2010-12-29, 1389/10/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-29, 1389/10/08

Registrant information

Name

Ashraf Jamal

Name of organization / entity

Tehran University Of Medical science

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Recruitment status

Recruitment complete

Funding source

Tehran university of medical science

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2011-09-21, 1390/06/30

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: **160****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**

Tehran University of Medical Sciences

Street address

Shariati Hospital, North Karegar Ave.

City

Tehran

Postal code**Approval date**

2009-02-15, 1387/11/27

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

Polycystic ovarian 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**

Gestational Diabet

Timepoint

at 24-28 weeks of pregnancy

Method of measurement

GCT

3**Description**

Preeclampsia

Timepoint

Monthly routine control of pregnancy

Method of measurement

Evaluation of BP and urine protein exam

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**

After uterine artery doppler 50% of control group received placebo similar to metformin 1 tablet BD, 50%

of control group received placebo similar to aspirin 1 tablet daily until delivery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Nafiseh Baradaran Rafiee

Street address

north karegar avu.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Asraf Ale Yasin

Street address

North karegar avu, Hospital Shariati,

City

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

Name of organization / entity

Shariati Hospital

Full name of responsible person

Dr.Nafiseh Baradaran Rafiee

Position

Perinatology Fellow

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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