

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 1722 9328

###### Email address

milani@gums.ac.ir

###### 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  
**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**  
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## Person responsible for scientific inquiries

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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*