

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effect of metformin in prevention from severe preeclampsia

Protocol summary

Study aim

Evaluation of the therapeutic effect of metformin in the prevention of preeclampsia

Design

Clinical randomized triple-blind, phase 3, 52 pregnant women with non-severe preeclampsia who presented for pregnancy care randomly (by lottery method) divided into two groups: metformin and placebo

Settings and conduct

Shahid Akbarabadi hospital and Firouzabadi hospital

Participants/Inclusion and exclusion criteria

inclusion criteria: Single pregnancies. Exclusion criteria: eclampsia, severe preeclampsia, kidney failure, insulin-treated diabetics, indications for termination of pregnancy other than hypertension, multiple pregnancies.

Intervention groups

Patients are divided two groups, metformin, 1000 mg per day in intervention group and placebo in control group and then people are followed until the end of pregnancy.

Main outcome variables

Incidence of severe preeclampsia and its maternal and fetal complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210316050725N1**

Registration date: **2021-05-28, 1400/03/07**

Registration timing: **prospective**

Last update: **2021-05-28, 1400/03/07**

Update count: **0**

Registration date

2021-05-28, 1400/03/07

Registrant information

Name

shahnaz Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5563 3244

Email address

ahmadishahnaz2005@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of metformin in prevention from severe preeclampsia

Public title

The effect of the metformin in preventing of the preeclampsia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Non severe preeclampsia Single pregnancy

Exclusion criteria:

Eclampsia Severe preeclampsia Renal failure Insulin -treated diabet

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyster

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description

After determining the total volume of the sample.papers A and B are placed in the lottery container. Then the papers are randomly removed from the container without replacement and the created sequence is recorded.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The person receiving the medication, the person giving the medication, and the person analyzing the results are unaware of the type of medication (metformin or placebo) used. Placebo (paper A) and metformin tablets (paper B) are poured in equal numbers in a bag. and at the time of the patient's visit who are eligible for the study, she is said to have picked up one of the papers. pills then given to the patient based on the patient's choice (blind) . (the resident who gives the pill does not know which group of placebo and which group is metformin due to the same packaging. she is blind .). The analyzer also reports the final results under groups A and B (without knowing the type of group).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran university of medical science

Street address

Molavi Street

City

Tehran

Province

Tehran

Postal code

1168743514

Approval date

2020-01-28, 1398/11/08

Ethics committee reference number

IR.IUMS.FMD.REC.1398.472

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

Non severe preeclampsia

ICD-10 code

O14.00

ICD-10 code description

Mild to moderate pre-eclampsia, unspecified trimester

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

Severe preeclampsia

Timepoint

Weekly untill term pregnancy

Method of measurement

Weekly visit , blood pressure assesment , laboratory assesment

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

Hypertension

Timepoint

Weekly visit

Method of measurement

with the help of mercury manometer

2**Description**

Fetal growth

Timepoint

Weekly

Method of measurement

Ultrasound

3**Description**

Elevated in liver enzyme

Timepoint

Weekly

Method of measurement

Laboratory

4**Description**

Headache, blurred vision , pain in epigaster

Timepoint

weekly
Method of measurement
Biography

5

Description
Blood creatinine in mother
Timepoint
Weekly
Method of measurement
Laboratory

6

Description
Diabet in mother
Timepoint
Monthly
Method of measurement
Assesment of Fast blood sugar and 2 hours after meal

7

Description
Fetal health assessment tests
Timepoint
Weekly
Method of measurement
Non stress test and biophysical profile

8

Description
Proteinurea
Timepoint
Weekly
Method of measurement
By collecting urine 24 hours a day

Intervention groups

1

Description
In the intervention group, pregnant woman with only high blood pressure is given 1000 mg of metformin during her entire pregnancy, and during the course of labor, the symptoms of severe preeclampsia and fetal growth are evaluated
Category
Treatment - Drugs

2

Description
In the control group, pregnant woman with only high blood pressure is given a placebo for the entire pregnancy and the symptoms of severe preeclampsia and fetal growth are assessed during labor.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabadi hospital and Firouzabadi hospital
Full name of responsible person
Shahnaz Ahmadi
Street address
Molavi street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Shahnaz Ahmadi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

paper

When the data will become available and for how long

one months after paper print

To whom data/document is available

all people

Under which criteria data/document could be used

Email

From where data/document is obtainable

Demandants can contact by Dr. Shahnaz Ahmadi, the principal investigator, or the education office of Akbrabadi Hospital via the email ahmadishahnaz2005@yahoo.com and call 02155633244

What processes are involved for a request to access data/document

respose one month after email

Comments