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
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Iran (Islamic Republic of)
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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:
Eclamsia Severe reeclamsia Renal failure Insulin -treated diabet
Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

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

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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