

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effectiveness of metformin in the prevention of preeclampsia in pregnant women at high risk of preeclampsia

Protocol summary

Study aim

Investigating the effectiveness of metformin in preventing preeclampsia in pregnant women

Design

Clinical trial with a control group, with parallel groups, without blinding, randomized, phase 2 on 160 patients. A table of random numbers was used for randomization.

Settings and conduct

This study will be conducted on pregnant mothers aged 18 to 45 who have a risk factor for preeclampsia in 1402 at Isfahan University of Medical Sciences. Blinding was not achieved in this study.

Participants/Inclusion and exclusion criteria

This study will be conducted in Isfahan University of Medical Sciences in 1402 on pregnant mothers who have a risk factor for preeclampsia and do not have any other underlying disease.

Intervention groups

People in the intervention group in this study are treated with metformin 500 daily from the 12th week of pregnancy. The control group does not receive drugs

Main outcome variables

preeclampsia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230730058975N1**

Registration date: **2023-08-12, 1402/05/21**

Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**

Update count: **0**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

vida Behzad Far

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 511 0976

Email address

behzadfar_neda@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of metformin in the prevention of preeclampsia in pregnant women at high risk of preeclampsia

Public title

Metformin in the prevention of preeclampsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 18 to 45 informed consent having risk factors for preeclampsia

Exclusion criteria:

underlying disease like diabetes

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done individually and simply. At first, according to the number of samples, random numbers are created with the help of a random number table and placed in each envelope. The envelopes are also numbered in order. According to the order of people entering the study, an envelope is opened and a random number is determined. If the random number is odd, they are placed in the first group and if it is even, they are placed in the second group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-09-07, 1401/06/16

Ethics committee reference number

IR.MUI.MED.REC.1401.223

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

preeclampsia

ICD-10 code

O14

ICD-10 code description

Pre-eclampsia

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

preeclampsia

Timepoint

Every two weeks from the 12th week of pregnancy

Method of measurement

history taking and physical examination

Secondary outcomes

empty

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

Intervention group: Metformin 500 mg tablets, produced by Iran Najo company, one daily from the 12th week of pregnancy

Category

Treatment - Drugs

2**Description**

Control group: No action or medicine

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra hospital

Full name of responsible person

Vida Behzadfar

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholmreza Asgari

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

vida Behzadfar

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Vida Behzadfar

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available