Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of Metformin and Aspirin compared to Aspirin on the prevention of Preeclampsia and the duration of pregnancy and some maternal and neonatal outcomes

Protocol summary

Study aim

Determining the effect of metformin in the prevention of preeclampsia in high-risk pregnancies Determining the effect of metformin during pregnancy in preeclampsia in high-risk pregnancies

Design

Eligible subjects were randomly divided into two groups: the control group (A) received 150 mg aspirin from weeks 12 to 20, and the intervention group (B) received 500 mg metformin twice daily in addition to 150 mg aspirin from weeks 12 to 20. It should be noted that the patient and the assessor were unaware of the group assignment and the study was double-blind

Settings and conduct

Eligible subjects were randomly divided into two groups: the control group received 150 mg aspirin from weeks 12 to 20, and the intervention group received 500 mg metformin twice daily from weeks 12 to 20 in addition to 150 mg aspirin. The patients and the assessor were unaware of the group assignment, and the study was double-blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Pregnant mothers aged 18 to 45 years - Gestational age 12 to 20 weeks 2- Mothers who are at moderate or high risk for preeclampsia according to the ACOG risk assessment table 3- Serum PAPP-A marker level at 12 weeks screening is less than 0.5 MOM 4- Mean bilateral uterine artery resistance index (PI) is greater than the 95th percentile for gestational age, on NT sonography (12 minutes) or anomalous scan ultrasound at 18 to 19 weeks. Exclusion criteria: 1- Sensitivity to metformin - Maternal unwillingness to take the drug 2- Major abnormality in anomalous scan 3- Abnormal karyotype in CVS (chorionic villus sampling) or amniocentesis

Intervention groups

Intervention group (B) In addition to 150 mg of aspirin, metformin 500 mg twice daily starting from weeks 12 to 20

Main outcome variables

Severe manifestations such as severe headaches, nausea and vomiting, and visual symptoms, and in the case of high blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251031067831N1**
Registration date: **2026-02-16, 1404/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-16, 1404/11/27**
Update count: **0**

Registration date

2026-02-16, 1404/11/27

Registrant information

Name

sima ghobadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 0164

Email address

ahmadimche@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-15, 1404/09/24

Expected recruitment end date

2026-03-15, 1404/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Metformin and Aspirin compared to Aspirin on the prevention of Preeclampsia and the duration of pregnancy and some maternal and neonatal outcomes

Public title

Investigating the effect of Metformin and Aspirin on the prevention of Preeclampsia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant mothers aged 18 to 45 years - gestational age 12 to 20 weeks Mothers who are at moderate or high risk for preeclampsia according to the ACOG risk assessment table Serum PAPP-A marker level at 12 weeks screening is less than 0.5 MOM Mean bilateral uterine artery resistance index (PI) is greater than the 95th percentile for gestational age, on NT sonography (12 minutes) or anomalous ultrasound scan at 18 to 19 weeks.

Exclusion criteria:

Sensitivity to metformin - maternal lack of consent to taking the medication Major abnormality in anomalous scan Abnormal karyotype on CVS (chorionic villus sampling) or amniocentesis

Age

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

Gender

Female

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

The blocking method will be used to allocate mothers to two groups. The advantages of blocked randomization are that it ensures a balance in the number of patients in each group. The groups are defined as codes B and A. Group A will be considered the intervention and group B the control. Before assigning individuals to one of the groups, a list of letters (B, A) is formed, called blocks. Each of the referring and eligible individuals will be assigned to one of the groups according to the created list. To avoid the risk of predicting the assignment of individuals to different groups, blocks of different sizes will be created. Blocks of two such as AB - blocks of four such as ABAB - blocks of six such as AABABB - blocks of eight such as ABBABABA

Blinding (investigator's opinion)

Single blinded

Blinding description

The drugs are coded according to the label A and B and are given to the intervention and control groups in such a way that the identity of the drug is not known to the patient. In order to blind the patients, both groups are given pregnancy supplements. The assessor who checks and measures the variables is faced with the label A and B and knows which drug each patient is taking. The pregnant mothers are not aware of being in the intervention or control group and are only divided into two groups A and B

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yasuj University of Medical Sciences

Street address

Yasuj, Shahid Motahari Boulevard

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591994759

Approval date

2025-05-03, 1404/02/13

Ethics committee reference number

IR.YUMS.REC.1404.010

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Preventing preeclampsia in high-risk mothers

Timepoint

Once every two weeks

Method of measurement

Questionnaire and data collection form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Metformin receiving group
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان امام سجاد یاسوج
Full name of responsible person
سیما قبادی
Street address
امام سجاد
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr. Sirous Saleh Nasab
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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
Yasouj 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
Yasouj University of Medical Sciences
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Sima Ghobadi
Position
Resident
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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
There is no further information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available