Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the effect of metformin and insulin combination therapy in comparison with the use of insulin alone in the prevention of preeclampsia in pregnant women with gestational diabetes

Protocol summary

Study aim
The effect of metformin 500milligram and insulin compared to the use of insulin in prevention of preeclampsia in pregnant women with gestational diabetes

Design
Clinical trial with control group, with parallel groups, randomized, on 150 patients. The rand function of Excel software was used for randomization.

Settings and conduct
This study will be conducted on 150 pregnant women with gestational diabetes referring to Alzahra, Shahid Beheshti and Amin hospital. After entering the study, patients are divided into intervention and control groups using a simple randomization method. Patients in the control group will be treated with insulin using a Intermediate-acting insulins such as neutral protamine Hagedorn with a starting dose of 2 units per kilogram, and in the intervention group, they will be treated with metformin and insulin, metformin 500 milligram twice a day.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational diabetes mellitus based on glucose challenge test or glucose tolerance test , age of 18-40 years, single pregnancy, gestational age between 20-34 weeks and fasting glucose testing over 95 milligram per deciliter or 2 hours postprandial blood sugar glucose over 120 milligram per deciliter Exclusion criteria: high blood pressure before pregnancy, history of any systemic disease (including cardiovascular, kidney Diseases, hepatic and autoimmune diseases), Addiction or drug abuse, Obesity (Body mass index above 30), overt diabetes, major neonatal malformations

Intervention groups
Patients in the intervention group will receive oral metformin 500 milligram twice a day and insulin according to the patient's needs until the day of delivery or termination of pregnancy. Patients in the control group will receive oral metformin 500 milligram twice a day until the day of delivery or termination of pregnancy

Main outcome variables
Symptoms of Preeclampsia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220107053652N1**
Registration date: **2022-11-26, 1401/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-26, 1401/09/05**
Update count: **0**

Registration date
2022-11-26, 1401/09/05

Registrant information

Name
Farinaz Farahbod

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3236 2191

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farinaz.farahbod@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of metformin and insulin combination therapy in comparison with the use of insulin alone in the prevention of preeclampsia in pregnant women with gestational diabetes

Public title
The effect of metformin and insulin in the prevention of preeclampsia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational diabetes Age of 18-40 years Single pregnancy Gestational age between 20-34 weeks Fasting glucose test more than 95 mg/dl or 2 hours postprandial glucose more than 120 mg
Exclusion criteria:
Having high blood pressure before pregnancy Previous history of any systemic disease (including cardiovascular, renal, hepatic, and autoimmune diseases) Addiction and drug abuse Obesity (Body mass index above 30) Overt diabetes Major neonatal malformations
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into two equal intervention and control groups by simple randomization method and using Rand function of Excel software. In this way, we type the expression (0,1)randbetween= in one of the cells of the Excel software, if the random number generated was 0, it is from insulin treatment alone, and if the number was observed, it was 1 from the combination treatment of metformin and insulin. We use and continue this work until all 150 patients are assigned to two intervention and control groups.
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
Shahid Dr. Beheshti Hospital,Motahari Street
City
Esfahan
Province
Isfehan
Postal code
8184853542
Approval date
2021-11-16, 1400/08/25
Ethics committee reference number
IR.MUI.MED.REC.1400.639

Health conditions studied

1

Description of health condition studied
Pre-eclampsia
ICD-10 code
014
ICD-10 code description
Pre-eclampsia

Primary outcomes

1

Description
Blood Pressure
Timepoint
Once every two weeks
Method of measurement
Using a sphygmomanometer

Secondary outcomes

1

Description
Weight
Timepoint
During the period of pregnancy
Method of measurement
Balance

2

Description
Fasting blood sugar

Timepoint
The periods during pregnancy
Method of measurement
Using a glucometer

3

Description
Blood sugar after eating
Timepoint
The periods during pregnancy
Method of measurement
Using a glucometer

4

Description
High proteins in the urine
Timepoint
The periods during pregnancy
Method of measurement
Using urine test

Intervention groups

1

Description
Intervention group: For the intervention group, oral metformin 500 milligram twice a day and insulin will be prescribed according to the patient's needs until the delivery or termination of pregnancy.
Category
Treatment - Drugs

2

Description
Control group: For the intervention group, oral metformin 500 milligram twice a day will be prescribed until the day of delivery or termination of pregnancy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Dr. Farinaz Farhbod
Street address
Al-Zahra Hospital, Safa Boulevard, Shahid Keshvari Highway, Isfahan, Iran
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2

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Medical School, Isfahan 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
Dr. Farinaz Farhbod
Position
Associate Professor, Faculty Physician
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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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
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