Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of metformin on the incidence of preeclampsia in pregnant women with low pregnancy-associated plasma protein A

Protocol summary

Study aim
The effect of metformin on the incidence of preeclampsia in pregnant women with low pregnancy-associated plasma protein A

Design
The current clinical trial study has a control group, with parallel groups, single-blind, randomized (using block randomization), phase 3 on 80 patients.

Settings and conduct
In this single-blind randomization clinical trial, pregnant women with low pregnancy-associated plasma protein A referring to Ayatollah Taleghani Hospital in Arak will be divided into two equal intervention and control groups by means of block randomization. In the intervention group, patients will receive metformin 500 mg oral tablets daily, and in the control group, they will receive placebo tablets daily. In this study, the patients are blinded by the identical appearance of the tablets. Finally, the two groups are compared in terms of outcomes.

Participants/Inclusion and exclusion criteria
Conditions for inclusion in the study: Pregnant mothers with low pregnancy-related plasma protein A referred to kousar Clinic, Normal arterial Doppler ultrasound; Age 18-50 years; Consent to participate in the study. Conditions for not entering the study: History of intrauterine growth restriction or preeclampsia, gestational hypertension or pregnancy complications in previous pregnancies; History of congenital disease; History of liver or kidney failure.

Intervention groups
Intervention group: Patients in this group will receive metformin 500 mg oral tablets of Exir pharmaceutical company once a day until the end of pregnancy. Control group: Patients in this group will receive an oral tablet similar to metformin made of starch daily until the end of pregnancy.

Main outcome variables
functional liver enzymes; systolic and diastolic blood pressure; proteinuria; Preterm delivery; low birth weight; Type of delivery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191104045328N14**
Registration date: **2022-12-26, 1401/10/05**
Registration timing: **prospective**

Last update: **2022-12-26, 1401/10/05**
Update count: **0**

Registration date
2022-12-26, 1401/10/05

Registrant information
Name
Amin Haji seyyed hoseini
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-01-10, 1401/10/20
Expected recruitment end date
2023-04-09, 1402/01/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
The effect of metformin on the incidence of preeclampsia in pregnant women with low pregnancy-associated plasma protein A

Public title
The effect of metformin on reducing preeclampsia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant mothers with low pregnancy-related plasma protein A referred to kousar Clinic Normal arterial Doppler ultrasound Age 18-50 years Consent to participate in the study

Exclusion criteria:
History of intrauterine growth restriction or preeclampsia, gestational hypertension or pregnancy complications in previous pregnancies History of congenital disease History of liver or kidney failure

Age
From **15 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be assigned to two intervention and control groups based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate the samples. In this way, using the site www.sealedenvelope.com, blocks of 8 letters A and B are randomly generated based on the sample size. The order of placement of letters A and B in each block from the first block to the last block is considered as a randomization sequence. The production of these blocks and their random sequence is completely done by this site and the researcher does not know how they are sequenced.

Blinding (investigator's opinion)
Single blinded

Blinding description
This trial is single-blind. For this purpose, one group will receive metformin tablets and the other group will receive a starch tablet similar to metformin, and the mothers participating in the study are not aware of the type of drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2022-06-13, 1401/03/23

Ethics committee reference number
IR.ARAKMU.REC.1401.138

Health conditions studied

1

Description of health condition studied
Pre-eclampsia

ICD-10 code
O14

ICD-10 code description
Pre-eclampsia

Primary outcomes

1

Description
Functional liver enzymes

Timepoint
in the 14th, 28th, 32nd weeks of pregnancy and at the time of delivery

Method of measurement
laboratory test

2

Description
Systolic and diastolic blood pressure

Timepoint
in the 14th, 28th, 32nd weeks of pregnancy and at the time of delivery

Method of measurement
Mercury sphygmomanometer

3

Description
proteinuria
Timepoint
in the 14th, 28th, 32nd weeks of pregnancy and at the time of delivery
Method of measurement
Urinalysis test

4

Description
Preterm delivery
Timepoint
Delivery between 20 and 37 weeks
Method of measurement
Delivery

5

Description
Low birth weight
Timepoint
Birth weight less than 2500 grams
Method of measurement
scales

6

Description
Type of delivery
Timepoint
How the baby is born
Method of measurement
Cesarean-vaginal

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group will receive metformin 500 mg oral tablets of Exir pharmaceutical company once a day until the end of pregnancy.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group will receive an oral tablet similar to metformin made of starch daily until the end of pregnancy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital, Arak
Full name of responsible person
Dr. Maryam Maktabi
Street address
Vice Chancellor for Education,Ayatollah Taleghani Hospital, Arak, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Mehdi Salehi
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Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Dr. Maryam Maktabi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Biostatistics

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Person responsible for updating data

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Full name of responsible person
Dr. Seyedeh Arzoo Afzal Shahidi

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Medical doctor

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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
After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long
Access will be from 2023/4/20 to 2026/4/20 for 3 years.

To whom data/document is available
University researchers

Under which criteria data/document could be used
Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable

University researchers and university professors, after contacting the respective professor by message or email, can request the utilization and use of data from Dr. Maryam Maktabi and then Dr. Seyedeh Arzoo Afzal Shahidi, respectively. Dr. Maryam Maktabi: Phone: 09121951402 Email: Dr.maryam.maktabi@gmail.com Address: Vice Chancellor for Education,Ayatollah Taleghani Hospital, Arak, Iran Dr. Seyedeh Arzoo Afzal Shahidi: Phone: 09153221459 Email: 15.a.shahidi@gmail.com Address: Vice Chancellor for Education,Ayatollah Taleghani Hospital, Arak, Iran

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

Letter writing should be done with professors and universities.

Comments