Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of using metformin versus not using on the incidence of gestational diabetes and preeclampsia in pregnant women with polycystic ovary: A randomized clinical trial

Protocol summary

Study aim
To assess the effect of using metformin versus not using on the incidence of gestational diabetes and preeclampsia in pregnant women with polycystic ovary

Design
This is a randomized clinical trial, phase III, in which 170 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible pregnant women with polycystic ovary who will refer to Fatemieh Hospital of Hamadan City during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 40 years; Pregnant; Polycystic Ovary Exclusion criteria: A history of repeated abortion; Uterine abnormality; A history of chronic diseases such as lupus and renal failure

Intervention groups
Intervention group: Routine care during pregnancy and tablet metformin 1000 to 2000 mg (1 or 2 tablets) daily until the end of pregnancy Control group: Just routine care during pregnancy

Main outcome variables
Primary outcome: Assessing gestational diabetes Assessing the preeclampsia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N252**
Registration date: **2018-11-24, 1397/09/03**
Registration timing: **prospective**

Last update: **2018-11-24, 1397/09/03**
Update count: **0**

Registration date
2018-11-24, 1397/09/03

Registrant information

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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
2018-12-06, 1397/09/15

Expected recruitment end date
2019-06-05, 1398/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of using metformin versus not using on the incidence of gestational diabetes and preeclampsia in pregnant women with polycystic ovary: A randomized clinical trial

Public title
Effect of using metformin on the incidence of gestational diabetes and preeclampsia in pregnant women with

polycystic ovary

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 40 years; Pregnant; Polycystic ovary

Exclusion criteria:

A history of repeated abortion; Uterine abnormality; A history of chronic disease such as lupus and renal failure

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we prepared 4 sheets of paper, writing on 2 sheets intervention and on 2 sheets control. The paper sheets were pooled and randomly drawn 1 at a time for each patient without replacement until all 4 sheets were drawn. The 4 paper sheets were then placed back into the container and this action repeated until the sample size was reached.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

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Province

Hamadan

Postal code

6517838695

Approval date

2018-10-12, 1397/07/20

Ethics committee reference number

IR.UMSHA.REC.1397.473

Health conditions studied

1

Description of health condition studied

Gestational diabetes

ICD-10 code

O24.41

ICD-10 code description

Gestational diabetes mellitus in pregnancy

2

Description of health condition studied

Pre-eclampsia

ICD-10 code

O14

ICD-10 code description

Pre-eclampsia

Primary outcomes

1

Description

Assessing the gestational diabetes

Timepoint

Every 3 months until end of pregnancy

Method of measurement

Through laboratory diagnostic test measuring blood glucose

2

Description

Assessing the preeclampsia

Timepoint

Every 2 weeks until end of pregnancy

Method of measurement

By physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care during pregnancy and tablet metformin 1000 to 2000 mg (1 or 2 tablets) daily until end of pregnancy

Category

Treatment - Drugs

2

Description
Control group: Just routine care during pregnancy
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Dr. Elham Ghasemi
Street address
Fatemieh Hospital, Pasdaran Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan 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
Hamedan 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
Hamedan University of Medical Sciences
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Dr. Elham Ghasemi
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Gynecologic Resident
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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