

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

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
Hamadan
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.

City

Hamadan

Province

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Postal code

6517838695

Phone

+98 81 3828 3939

Email

eghasemi1395@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Full name of responsible person

Dr. Elham Ghasemi

Position

Gynecologic Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Shohreh Alimohamadi

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

poorolajal@umsha.ac.ir

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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