Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative Efficacy of Extended-released Versus Immediate-release Metformin on Glycemic Control in Women with Gestational Diabetes Mellitus:A Randomized Controlled Trial

Protocol summary

Study aim

This study aims to compare the efficacy of extended-release (XR) and immediate-release (IR) metformin in controlling blood glucose levels among women with gestational diabetes mellitus (GDM). Adverse effects and tolerability will also be compared.

Design

Two-arm, parallel-group, open-label randomized controlled trial designed to compare the efficacy of two metformin formulations in women with gestational diabetes mellitus. Participants will be assigned to two treatment groups using block randomization with a 1:1 allocation ratio.

Settings and conduct

The study will be conducted at Ghaem Hospital, Mashhad, Iran. Eligible women with GDM will be randomly assigned to XR or IR metformin. Fasting and postprandial glucose levels, adverse effects, and the need for insulin therapy will be assessed.

Participants/Inclusion and exclusion criteria

Women aged 18–45 years with singleton pregnancies at 24–26 weeks of gestation, diagnosed with GDM by OGTT, will be enrolled after informed consent. Exclusion criteria include interacting medications, creatinine >1.2 mg/dL, metformin hypersensitivity, heart failure, myocardial infarction, moderate to severe pulmonary disease, and adrenal or pituitary insufficiency.

Intervention groups

Participants will receive either IR or XR metformin, starting at 500 mg with dinner. Doses will be adjusted according to the study protocol based on glycemic control. Blood glucose levels and adverse effects will be monitored in both groups.

Main outcome variables

Fasting blood glucose (FBG), one-hour postprandial blood glucose, and two-hour postprandial blood glucose levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130914014649N5**
Registration date: **2026-11-16, 1405/08/25**
Registration timing: **registered_while_recruiting**

Last update: **2026-11-16, 1405/08/25**
Update count: **0**

Registration date

2026-11-16, 1405/08/25

Registrant information

Name

Fatemeh Tara

Name of organization / entity

Omolbanin Hospital, Taghiabad Avenue

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-12, 1405/08/21

Expected recruitment end date

2026-12-06, 1405/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative Efficacy of Extended-released Versus Immediate-release Metformin on Glycemic Control in Women with Gestational Diabetes Mellitus:A Randomized Controlled Trial

Public title
Comparing the Effects of Extended-Release and Immediate-Release Metformin on Blood Sugar Control in Women with Gestational Diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women aged 18-45 years with singleton pregnancies at 24-26 weeks of gestation Diagnosed of gestational diabetes mellitus (GDM) based on an oral glucose tolerance test (OGTT)

Exclusion criteria:
Use of medications that interact with metformin or affect blood glucose levels Serum creatinine greater than 1.2 mg/dl History of known hypersensitivity to metformin Heart failure History of myocardial infarction Moderate to severe pulmonary disease Adrenal insufficiency Pituitary insufficiency

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

Gender
Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **37**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, eligiblepatients will be randomly assigned to two groups receiving either extended-released metformin (xr) or immediate-released metformin (ir) after providing informed consent. Block randomization with a1:1 allocation ratio will be used. The random allocation sequence will be generated using the online Sealed Enveloped randomization tool with block sizes of 4 and 6.

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 Mashhad University of Medical Sciences

Street address
Ahmadabad Street, Ghaem Hospital, Mashhad, Iran.

City
Mashhad

Province
Razavi Khorasan

Postal code
9175835743

Approval date
2026-09-21, 1405/06/30

Ethics committee reference number
IR.MUMS.IRH.REC.1405.142

Health conditions studied

1

Description of health condition studied
Gestational Diabetes Mellitus

ICD-10 code
O24.4

ICD-10 code description
Gestational diabetes mellitus

Primary outcomes

1

Description
Fasting Blood Glucose

Timepoint
At baseline (24-26 weeks of gestation), during treatment follow up, and at delivery.

Method of measurement
FBS will be measured after at least 8 hours of fasting using a glucometer or laboratory blood glucose testing, expressed in mg/dl.

2

Description
One hour Postprandial Blood Glucose

Timepoint
At baseline (24-26 weeks of gestation), during treatment follow up, and at delivery.

Method of measurement
Blood Glucose will be measured one hour after the start of a meal, using a glucometer or laboratory blood glucose testing, expressed in mg/dl.

3

Description
Two hour Postprandial Blood Glucose

Timepoint
At baseline (24-26 weeks of gestation), during treatment follow up, and at delivery.
Method of measurement
Blood Glucose will be measured two hour after the start of a meal, using a glucometer or laboratory blood glucose testing, expressed in mg/dl.

Secondary outcomes

1

Description
Incidence of adverse effects associated with extended-release and immediate-release metformin.
Timepoint
From treatment initiation, during follow-up visits until delivery.
Method of measurement
Assessment and recording of patient-reported adverse effects and physician evaluations throughout treatment.

2

Description
Number and percentage of patients requiring insulin therapy due to inadequate glycemic control with metformin.
Timepoint
From metformin initiation, during follow-up visits until delivery.
Method of measurement
Review of medical records to identify patients who require initiation of insulin therapy due to inadequate glycemic control, based on the treating physician’s assessment.

Intervention groups

1

Description
Intervention group: Pregnant women diagnosed with gestational diabetes mellitus will receive extended-release metformin (XR). Treatment will be initiated at an oral dose of 500 mg once daily with dinner. The dose will be adjusted according to blood glucose levels and patient tolerability, based on the study protocol. Treatment will continue until delivery.
Category
Treatment - Drugs

2

Description
Intervention group: Pregnant women diagnosed with gestational diabetes mellitus will receive immediate-release metformin (IR). Treatment will be initiated at an oral dose of 500 mg once daily with dinner. The dose will be adjusted according to blood glucose levels and patient tolerability, based on the study protocol. Treatment will continue until delivery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Zahra Motevasselian
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Ghaem Hospital, Ahmadabad Street, Mashhad, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Motevasselian

Position

Resident in Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Resident in Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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