Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessing the efficacy of the prophylactic metformin administration in the prevention of gestational diabetes mellitus in non-diabetic obese pregnant women referred to Motahari Teaching Hospital

Protocol summary

Study aim

Main goal: Assessing the efficacy of prophylactic metformin administration in the prevention of gestational diabetes mellitus in non-diabetic obese pregnant women referred to Mottahari Hospital (Urmia) Specific goals: Comparing the requirement of insulin administration between groups Comparing the final insulin dosage between groups Comparing the incidence of polyhydramnios between groups Comparing the incidence of preterm labor between groups Comparing the cesarean section between groups Comparison of infant hospitalization in the intensive care unit between groups

Design

This clinical trial aims to enroll 342 eligible patients. Block randomization will be performed to stratify patients into the control and intervention groups. The main group will receive metformin, while the controls will be exempt from receiving metfromin or placebo.

Settings and conduct

After enrolling eligible patients, metformin administration will commence as explained. A two-hour glucose tolerance test (75gr) will be performed between weeks 24 and 28 of pregnancy. Positive patients will be referred to a perinatologist and treated if necessary. Screening for polyhydramnios will be performed throughout the third trimester. The following factors will be taken into consideration at the time of delivery: final insulin dosage, method of delivery, indications of cesarean section, gestational age and hospitalization at the intensive care unit

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age >16 years Gestational age >3 months Singleton pregnancy Exclusion criterias: Fetal anomalies Multifetal pregnancy History of overt diabetes mellitus

Intervention groups

The intervention group will receive metformin (500 mg every 12 hours; oral), starting from the 12th week of pregnancy until delivery

Main outcome variables

Frequency of GDM Required insulin dosage in GDM patients Frequency of polyhydramnios

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200113046112N1**
Registration date: **2020-03-17, 1398/12/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-17, 1398/12/27**
Update count: **0**

Registration date

2020-03-17, 1398/12/27

Registrant information

Name
Shiva Ghayor

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 44 3222 3629

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broumand.f@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-18, 1398/10/28

Expected recruitment end date

2020-07-18, 1399/04/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the efficacy of the prophylactic metformin administration in the prevention of gestational diabetes mellitus in non-diabetic obese pregnant women referred to Motahari Teaching Hospital

Public title

Prophylactic properties of metformin in the prevention of gestational diabetes mellitus

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age >16 years Gestational age <3 months Singleton pregnancy Body mass index ≥30

Exclusion criteria:

Multifetal pregnancy Fetal anomaly Previous history of diabetes mellitus, gestational diabetes mellitus, impaired fasting glucose or impaired glucose tolerance test History of corticosteroid use Heavy alcoholism History of adverse or allergic reactions to metformin History of underlying medical conditions (e.g. hypertension, renal failure, liver disease, malabsorption)

Age

From **16 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **342**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be performed to stratify patients into two groups: intervention and control. Each block will include 6 patients. All possible combinations of AAABBB will be listed and coded individually. Considering a study population of 342 patients, randomization of patients into 57 blocks is required. Blocks will be assigned to either groups in an alternating order.

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 Urmia University of Medical Sciences

Street address

orjhans Ave., Resalat Blvd

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Postal code

57147833

Approval date

2020-01-01, 1398/10/11

Ethics committee reference number

IR.UMSU.REC.1398.388

Health conditions studied

1

Description of health condition studied

Gestational Diabetes Mellitus in obese pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Incidence of gestational diabetes mellitus

Timepoint

Between weeks 24 and 28 of pregnancy

Method of measurement

Through the performance of two-hour glucose tolerance test with 75 grams of glucose

Secondary outcomes

1

Description

Requirement of insulin administration in the setting of gestational diabetes mellitus

Timepoint

Since the 24th week of pregnancy until time of delivery

Method of measurement

Questionnaire

2

Description

Final dosage of administered insulin at the time of

delivery

Timepoint

One day prior to delivery

Method of measurement

Patient documentations

3

Description

the incidence of polyhydramnios

Timepoint

Final pregnancy trimester

Method of measurement

Ultrasound imaging

4

Description

Incidence of preterm labor

Timepoint

At the time of delivery

Method of measurement

Assessment of gestational age will be performed based on ultrasound imaging and previously documented data pertaining to the current pregnancy

5

Description

Frequency of performed Cesarean Sections

Timepoint

At the time of delivery

Method of measurement

Hospitalization documents or by researcher designed questionnaire

6

Description

Frequency of hospitalization at the neonatal intensive care unit

Timepoint

At the time of birth

Method of measurement

Researcher designed questionnaire or hospitalization documentations

Intervention groups

1

Description

Administration of metformin(as F.C.Tablets metformin hydrochloride, manufactored in Iran, Kharazmi/ 500 mg every 12 hours; oral) starting from the 12th week of pregnancy until the time of delivery

Category

Prevention

2

Description

Control group: They will not be prescribed medication and will undergo routine pregnancy care and follow-up.

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Hospital

Full name of responsible person

Farzaneh Broumand

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Orjans Ave., Resalat Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Iraj Mohebbi

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Shiva Ghayor
Position
Resident of Obstetrics and Gynecology
Latest degree
Medical doctor
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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