Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Evaluating the effect of Metformin administration on pregnancy outcomes in healthy overweight pregnant women

Protocol summary

Study aim

Main goal: Evaluating the effect of Metformin administration on pregnancy outcomes in healthy overweight pregnant women specific goals: 1. comparing the frequency of GDM between the main and control groups 2.comparing the frequency of fetal macrosomia between the main and control groups 3. comparing the frequency of preeclampsia between the main and control groups 4.comparing the frequency of abnormal gestational weight gain between the main and control groups 5.comparing the frequency of neonatal hypoglycemia between the main and control groups 6.comparing the frequency of neonatal mortality between the main and control groups

Design

This double blinded RCT will enroll subjects and controls (n:170; 170), administrating metformin (1gr/day) and placebo, until delivery.

Settings and conduct

The main and control (n:170; 170) group will receive metformin (1gr/day) and placebo, respectively, until delivery. At GA: 24-28w, patients will undergo an oral glucose (75gr) challenge test. Estimated birth weight and growth percentile will be assessed twice (GA:32-34 & 37w). Gestational weight gain and the incidence of preeclampsia, fetal hypoglycemia, fetal death and birth defects will also be recorded.

Participants/Inclusion and exclusion criteria

All regnant mothers (GA:12-16 weeks; Singleton; 25<=BMI<30) visitng perinatology clinics of Motahari Hospital will be invited to participate. Those with a history of any general medical condition (e.g. DM, Hepatic disorderrs, hypertension) will be excluded.

Intervention groups

The main and control (n:170; 170) group will receive metformin (1gr/day) and placebo, respectively.

Main outcome variables

Incidence of fetal macrosomia Incidence of Gestational diabetes mellitus Incidence of preeclampsia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190716044229N1**
Registration date: **2020-02-06, 1398/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-06, 1398/11/17**
Update count: **0**

Registration date

2020-02-06, 1398/11/17

Registrant information

Name

Samira Esmaili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3367 9124

Email address

samiraesmaili2019@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-16, 1398/04/25

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Metformin administration on pregnancy outcomes in healthy overweight pregnant women

Public title
Impact of metformin on pregnancy outcomes in overweight women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Maternal age >=16 years Singelton pregnancy Body mass index: 25<=BMI<30 Negative history of Diabetes Mellitus Negative history of previous medical conditions Gestational age between 12 & 16 weeks
Exclusion criteria:
Multiple gestation Positive history of general medical conditions (e.g. diabetes) BMI<25 or >=30
Age
From **16 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **350**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be performed by an epidemiologist, via employing specialized software. Blocks A and B, each, shall only include patients form the intervention or control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
At the start of the study, each patient will be assigned an individual code, which will be used for identification thereafter. These codes will be also be used for randomization and shall only be available and accessible to the individual in charge of coding and grouping the subjects. Intervention and control groups will remain unrevealed to both physician and patient until the conclusion of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Urmia University of Medical Sciences
Street address
Orjhans Street, Resalat Blvd, Urmia , Iran
City
Urmia
Province
West Azarbaijan
Postal code
57147833
Approval date
2019-07-16, 1398/04/25
Ethics committee reference number
IR.UMSU.REC.1398.143

Health conditions studied

1

Description of health condition studied
Pregnancy outcomes in overweight pregnancies
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Frequency of fetal macrosomia
Timepoint
Post-partum
Method of measurement
Neonatal weighing scale

2

Description
Incidence of gestational diabetes mellitus
Timepoint
From gestational age 24 weeks onward
Method of measurement
Three hour glucose tolerance test

3

Description
Incidence of preeclampsia
Timepoint
Fromgestational age 20 weeks onward
Method of measurement
Measurement of blood pressure and relevant laboratory analyses

4

Description
Gestational weight gain monitoring
Timepoint
From baseline until delivery
Method of measurement
Weighing scale

Secondary outcomes

empty

Intervention groups

1

Description
Intevention group:oral metformin500 mgr/twice a day,(manufactured in Iran) from 12-16week until delivery
Category
Prevention

2

Description
Control group:placebo with chemical composition:(Starch200mg/Cellulose acetate 150 mg/Hypermellose50mg/Sodium lauryl sulfate50mg/Manesium stearate50mg).Round and white in Metformin size.construction of Urmia School of Pharmacy.Laboratory of Pharmaceuticals.twice a dayfrom 12-16 week until delivery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari hospital
Full name of responsible person
Shabnam vazifekhah
Street address
Kosar center (Department of obstetrics and perinatolgy), Motahari Hospital, Kashani st.
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51147
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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
Street address
Orjans Street.Resalat Blvt, Urmia, Iran
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urmia
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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
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
Samira Esmaili
Position
Resident of Obstetrics & 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
Resident of Obstetrics & Gynecology

Latest degree
Medical doctor

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Person responsible for updating data

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Full name of responsible person
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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