

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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; $25 \leq \text{BMI} < 30$) visitng perinatology clinics of Motahari Hospital will be invited to participate. Those with a history of any general medical condition (e.g. DM, Hepatic disorders, 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

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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: $25 \leq \text{BMI} < 30$ 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) $\text{BMI} < 25$ 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 committee 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

Intervention 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/Hypromellose50mg/Sodium lauryl
sulfate50mg/Magnesium 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 vazifekhan

Street address

Kosar center (Department of obstetrics and
perinatology), Motahari Hospital, Kashani st.

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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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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

Contact

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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