

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Compare the effect of metformin versus insulin in controlling blood sugar of gestational diabetes mellitus

Protocol summary

Summary

This clinical trial study will be conducted to compare the efficacy of metformin versus insulin in controlling blood sugar of gestational diabetes mellitus. All pregnant women with 18-40 years old at 24 to 28 weeks of gestational age, diagnosed as gestational diabetics by the glucose tolerance test, will enter the study by convenience sampling. All subjects will be recommended a diabetes diet and exercise for at least an hour of daily walking and they will be asked to measure and record their fasting blood sugar and 2 hours after a meal by using a glucometer at home. Then 280 people who, despite diet and exercise within at least one week, have high fasting blood glucose and 2 hours after a meal more than 95 and 120 respectively, will be allocated by block randomization in the two intervention (140 patients) and control groups (140 persons). In the intervention group, treatment with metformin will be started with a daily dose of 500 mg and this amount will be adjusted maximally to 1500 mg in two weeks according to blood glucose. During the treatment with maximum doses of metformin, those whose fasting blood sugar remain greater than 95 and their two-hour blood glucose higher than 120 will be omitted and replace by new people. In the control group, subcutaneous injection of 0.7 IU / kg insulin will be started and increased based on blood glucose recorded daily by patients. During the study, monitoring treatment process is self- monitoring blood glucose (SMBG). Finally, the average FBS and HPP 2 after lunch and dinner, pregnancy outcomes such as type of delivery, birth weight, Apgar score, need for NICU by midwives collaborator who is not informed of the intervention, will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080229172N1**

Registration date: **2017-01-06, 1395/10/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-06, 1395/10/17

Registrant information

Name

Samaneh Firouz

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 58 3722 3393

Email address

firouzs921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology affairs of Mashhad University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of metformin versus insulin in controlling blood sugar of gestational diabetes mellitus

Public title

Comparing the effect of metformin versus insulin in controlling the blood sugar in of gestational diabetic mother

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnancy more than 24 weeks with gestational diabetes mellitus; singleton pregnancy; uncontrolled blood sugar with diet and exercise within a week; informed consent to participate in this project. Exclusion criteria: overt diabetes; presence of risk factors for lactic acidosis; fetal anomaly; maternal medical conditions such as kidney and liver disease; not-attending for follow up.

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: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be done by close pocket method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Presidential area of Mashhad University of Medical Sciences, Qureshi Building, Daneshgah st, Mashhad

City

Mashhad

Postal code

Approval date

2016-05-06, 1395/02/17

Ethics committee reference number

IR.MUMS.fm.REC.1394.360

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

O24.4

ICD-10 code description

Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description

Fast blood sugar

Timepoint

At baseline, on a daily basis until the end of pregnancy

Method of measurement

Blood sugar test / Ican glucometer, On call Model

2

Description

Blood glucose two hours after a meal

Timepoint

At baseline, on a daily basis until the end of pregnancy

Method of measurement

Blood sugar test / Ican glucometer, On call Model

Secondary outcomes

1

Description

Type of delivery

Timepoint

Postpartum

Method of measurement

Reporting (Natural, Caesarean)

2

Description

Birth weight

Timepoint

Postpartum

Method of measurement

Measuring with Germany seca Digital Scale

3

Description

Apgar score

Timepoint

Postpartum

Method of measurement

Measuring based on the standard Apgar score

4

Description

need for NICU

Timepoint

Postpartum

Method of measurement

Reporting (have or have not)

Intervention groups

1

Description

In the intervention group, treatment with metformin will be started with a daily dose of 500 mg and this amount will be adjusted maximally to 1500 mg in two weeks according to blood glucose

Category

Treatment - Drugs

2

Description

In the control group, subcutaneous injection of 0.7 IU / kg insulin will be started and increased based on blood glucose recorded daily by patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Clinic of Imam Reza Hospital (AS)

Full name of responsible person

Nayyere Ghomian

Street address

Imam Reza hospital, Emam Reza Square, Ibn Sina St, Mashhad

City

Mashhad

2

Recruitment center**Name of recruitment center**

Omolbanin hospital

Full name of responsible person

Farideh Akhlaghi

Street address

Omolabanin hospital, Shahid Hasheminejad st, Mashhad

City

Mashhad

3

Recruitment center**Name of recruitment center**

Ghaem hospital

Full name of responsible person

Samaneh Firouz

Street address

Ghaem hospital, Ahmadabad st, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor for Research of Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Second floor, Faculty of Medicine, Ferdowsi University Campus, Azadi square, Mashhad

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Samaneh firouz

Position

Resident of gynecological surgery

Other areas of specialty/work**Street address**

Second floor, Faculty of Medicine, Ferdowsi University Campus, Azadi Square, Mashhad

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nyyere Ghomian

Position

Associate Professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Samaneh Firouz

Position

Resident of gynecological surgery

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty