Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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+98 58 3722 3393
Fax
Email

firouzs921@mums.ac.ir

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

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

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+98 51 3802 2608

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Email
ghomiann@mums.ac.ir

Web page address

Person responsible for updating data

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

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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