

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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

**City**

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**Postal code****Phone**

+98 58 3722 3393

**Fax****Email**

firouzs921@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Nyyere Ghomian

**Position**

Associate Professor

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## 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**

**Street address**

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

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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*