

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Metformin compared with insulin in control of blood sugar in gestational diabetes mellitus

#### Protocol summary

##### Summary

In this randomized single blind clinical trial, the efficacy of metformin with insulin for glycemic control and obstetrical complications in gestational diabetes mellitus are compared. Total 160 women 18 to 40 years with singleton pregnancy and gestational age between 20 to 34 weeks without underlying systemic disease with a diagnosis of GDM based on 2 or more abnormal values in 100 g oral glucose tolerance test (GTT) are studied. Women who failed diet therapy after one week with exist of two times (FBS> 95 mg / dl, BS> 120 mg / dl) were recruited randomly to receive either metformin (n=80) or insulin therapy (n=80) after getting a written consent .In the case group, metformin was given at a dose of 500 mg two times a day to a maximum of 2500 mg/day based on glycemic profile. In the control group, Insulin was started and titrated based on plasma glucose values. The goal of therapy is to have fasting glucose level <95 mg/dL and 2 hours postprandial level<120mg/dL.In the metformin group, insulin is added with two abnormal glucose profiles during the two weeks after reaching the maximum dose. Secondary outcomes are included maternal and fetal prognosis. Maternal outcomes are including preeclampsia, gestational hypertension, preterm delivery and cesarean section. Fetal and neonatal prognosis including mortality, macrosomia, LGA, SGA, hypoglycemia, Hyperbilirubinemia, hypocalcaemia, birth trauma, respiratory distress and NICU admission.

#### General information

##### Acronym

MiG trial

##### IRCT registration information

IRCT registration number: **IRCT201105075591N2**

Registration date: **2011-05-31, 1390/03/10**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-05-31, 1390/03/10

##### Registrant information

###### Name

Azin Alavi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2290 7454

###### Email address

alavi-a@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of medical sciences, principal investigator

##### Expected recruitment start date

2010-12-06, 1389/09/15

##### Expected recruitment end date

2011-12-06, 1390/09/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Metformin compared with insulin in control of blood sugar in gestational diabetes mellitus

##### Public title

Metformin in the management of gestational diabetes mellitus

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: 1 - 18 to 40 years old pregnant women  
2 - Singleton Pregnancy 3 - gestational age between 20 to 34 weeks (based on reliable LMP or ultrasound before 20 weeks of gestation) 3 - Diagnosis of GDM based on 2 or more abnormal values in GTT as per Carpenter and Coustan's criterion. Exclusion criteria: 1 - Systemic underlying disease (cardiovascular, pulmonary, renal , liver and autoimmune) 2 - Substance Abuse 3- Overt diabetes mellitus (except previous history of GDM)

### **Age**

From **18 years** old to **40 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **160**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Tehran University of medical sciences

##### **Street address**

Ghods St., Keshavarz Blvd

##### **City**

Tehran

##### **Postal code**

1417653761

#### **Approval date**

2011-02-27, 1389/12/08

#### **Ethics committee reference number**

89/130/2025

## **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**

plasma glucose

#### **Timepoint**

twice a week

#### **Method of measurement**

laboratory (mg/dl)

## **Secondary outcomes**

### **1**

#### **Description**

preeclampsia

#### **Timepoint**

Antenatal and postpartum

#### **Method of measurement**

blood pressure (mmhg),proteinuria (mg/dl)

### **2**

#### **Description**

preterm delivery

#### **Timepoint**

postnatal

#### **Method of measurement**

gestational age (week)

### **3**

#### **Description**

cesarean section

#### **Timepoint**

tim of delivery

#### **Method of measurement**

mode of delivery

### **4**

#### **Description**

perinatal mortality

#### **Timepoint**

antenatal,neonatal period

#### **Method of measurement**

IUFD,Still birth,neonatal death

### **5**

#### **Description**

macrosomia

#### **Timepoint**

birth time

#### **Method of measurement**

birth weight(kg)

## 6

### **Description**

hypoglycemia

### **Timepoint**

1st 24hr after birth

### **Method of measurement**

laboratory (mg/dl)

## 7

### **Description**

NICU admission

### **Timepoint**

neonatal period

### **Method of measurement**

day

## **Intervention groups**

### 1

#### **Description**

In the intervention group, metformin 500 mg tablet was given twice a day to a maximum of 2500 mg/day based on glycemic profile that begins from 20 to 34 weeks gestational age and continue throughout of pregnancy.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

In the control group, insulin 0.5 IU / kg as subcutaneous injection was started and titrated based on plasma glucose values from gestational age of 20 to 34 weeks and continue throughout of pregnancy.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Zanan Hospital (Mirzakuchak khan)

##### **Full name of responsible person**

Dr. Shirin Niromanesh

##### **Street address**

Zanan Hospital, Ostad nejatollahi shomali St.

##### **City**

Tehran

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Shariati Hospital

##### **Full name of responsible person**

Dr. Alavi Azin

##### **Street address**

Shariati Hospital, Kargar shomali

#### **City**

Tehran

### 3

#### **Recruitment center**

##### **Name of recruitment center**

Valiasr Hospital

##### **Full name of responsible person**

Dr. Sanaz Moosavi

##### **Street address**

Keshavarz blvd

##### **City**

Tehran

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Dr. Akbar Fotouhi

##### **Street address**

Ghods St., Keshavarz Blvd

##### **City**

Tehran

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Dr. Azin Alavi

##### **Position**

Obstetrician and Gynecologist, Fellowship of Perinatology

##### **Other areas of specialty/work**

##### **Street address**

Zanan Hospital, Ostad nejatollahi shomaly St.

##### **City**

Tehran

**Postal code**  
**Phone**  
+98 21 8889 7764  
**Fax**  
**Email**  
alavi-a@razi.tums.ac.ir  
**Web page address**

+98 21 8889 7764  
**Fax**  
**Email**  
alavi-a@razi.tums.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr. Azin Alavi  
**Position**  
Obstetrician and Gynecologist  
**Other areas of specialty/work**  
**Street address**  
Zanan Hospital, Ostad nejatollahi shomali St.  
**City**  
Tehran  
**Postal code**  
**Phone**

## Person responsible for updating data

### Contact

## 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*