

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Obstetrician and Gynecologist
Other areas of specialty/work
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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