Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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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
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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
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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