# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Comparison of newborn outcomes in women with gestational diabetes treated with metformin or insulin

## Protocol summary

**Summary**

Because of the importance of treating gestational diabetes, this trial is performed to compare maternal and neonatal outcomes in woman with gestational diabetes mellitus (GDM) treated with either metformin or insulin. 200 women with singleton pregnancy and without history of diabetes mellitus at the age of 24-34 weeks of pregnancy are included and divided randomly in two groups including 100 women treated with insulin and 100 women treated with metformin. Women with history of diabetes mellitus, renal or liver dysfunction and fetal growth restriction are excluded. Insulin or metformin will be prescribed and so target capillary glucose values of 95mg/dl (fasting) and 120mg/dl (2 hours postprandial) are gained. Data in two groups are analyzed and compared by computer methods after end of sampling. These include delivery method, apgare of 1st & 5th minute, neonatal anomalies, birth weight, and birth weight centile, hypoglycemia up to 3 hours after delivery, respiratory distress, special care baby unit and NICU admission.

## General information

**Acronym**

GDM

**IRCT registration information**

IRCT registration number: **IRCT201104162699N5**
Registration date: **2011-05-13, 1390/02/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2011-05-13, 1390/02/23

**Registrant information**

**Name**

Farzaneh Saberi

**Name of organization / entity**

Kashan University Of Medical Siences

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

Kashan University of Medical Sciences.Vice Chancellor for Research

**Expected recruitment start date**

2010-11-01, 1389/08/10

**Expected recruitment end date**

2011-08-22, 1390/05/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of newborn outcomes in women with gestational diabetes treated with metformin or insulin

**Public title**

Comparison of metformin and insulin in treatment of gestational diabetes

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Gestational diabet in Iranian women, the age of 18-45 years, singleton pregnancy , gestational age of 24-34 weeks ,no history of previous diabetes mellitus. Exclusion criteria: Previous diabetes mellitus before pregnancy, liver dysfunction, renal dysfunction,

intra uterine growth restriction, fetal anomaly, premature rupture of membrane, acute respiratory failure and congestive heart failure in mother

**Age**
From **18 years** old to **45 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **200**

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

**Randomization description**

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
kashan medicine univercity

**Street address**
Kashan University of Medical Sciences.kilometer of 5 Ravand way.

**City**
kashan

**Postal code**
81151-87159

**Approval date**
2010-12-29, 1389/10/08

**Ethics committee reference number**
2856/1/5/29/پ

## Health conditions studied

### 1

**Description of health condition studied**
Gestational diabetes mellitus

**ICD-10 code**
O24.9

**ICD-10 code description**
Diabetes mellitus in pregnancy, unspecified

## Primary outcomes

### 1

**Description**
Post partum hypoglycemia

**Timepoint**
3 first post partum houre

**Method of measurement**
Newborn blood sampling of Bs mg/dl

### 2

**Description**
Macrosomia

**Timepoint**
post partum

**Method of measurement**
Weighting of newborn ,gram with SECA scale

## Secondary outcomes

### 1

**Description**
neonatal icter

**Timepoint**
until 1 week after delivery

**Method of measurement**
Newborn bilirubin blood sampling mg/dl

### 2

**Description**
Fetal anomaly

**Timepoint**
post partum

**Method of measurement**
Observe and physical exam of newborn

### 3

**Description**
Respiratory distress

**Timepoint**
until 24 hours after delivery

**Method of measurement**
Observe and physical exam of newborn

### 4

**Description**
Admitting to neonatal unit

**Timepoint**
untill 1 week after delivery

**Method of measurement**
admition in neonatal unit

## Intervention groups

**1**

**Description**
for metformin group:tablet metformin 500mg,1-5daily,oral,untill end of pregnancy
**Category**
Treatment - Drugs

**2**

**Description**
for insulin group : NPH and regular Insulin , 0.5 U/kg daily in 2/3morning and1/3 night,sc,untill end of pregnancy
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shabihkhani hospital
**Full name of responsible person**
Dr.E.Mesdaghi nia
**Street address**
Medical faculty,Kashan University of Medical Sciences
**City**
Kashan

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice Chancellor for Research
**Full name of responsible person**
Dr Gholam Ali Hamidi
**Street address**
Kashan University of Medical Sciences
**City**
kashan
**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
**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**
Kashan medical univercity/Nursing and Midwifery School
**Full name of responsible person**
Farzaneh Saberi
**Position**
master of science/faculty member
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## Person responsible for scientific inquiries

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Obstetrics & gynecologist
**Other areas of specialty/work**
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## Person responsible for updating data

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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*