

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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 Sciences

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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 diabetes 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 hour

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

admission 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

Other areas of specialty/work

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Other areas of specialty/work

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Position

obstetrics & Gynecologist

Other areas of specialty/work

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Fax

Email

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