Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 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

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

saberi_f@kaums.ac.ir

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
Other areas of specialty/work
Street address
Kashan - Ghotb ravandyBULV - pezeshk BULV
City
Kashan
Postal code
Phone
+98 36 1555 0021
Fax
Email
saberi_f2002@yahoo.com saberi_f@kaums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan medical univercity
Full name of responsible person
Dr Elahe Mesdaghi nia
Position
Obstetrics & gynecologist
Other areas of specialty/work
Street address
Shabih khani hospital,Shahid Beheshti street,Kashan
City
Kashan
Postal code
Phone
+98 36 1446 0180
Fax
Email
mesdaghiniaelahe@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kashan medical univercity
Full name of responsible person
Dr Elahe Mesdaghi nia
Position
obstetrics & Gynecologist
Other areas of specialty/work
Street address
Kashan - Ghotb ravandyBULV - pezeshk BULV
City
Kashan
Postal code
Phone

+98 36 1555 0021

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