Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of glibenclamide in women with gestational diabetes on maternal and neonatal outcomes

Protocol summary

Summary

Due to the importance of treatment of gestational diabetes, the research will be conducted to assess the effect of maternal and neonatal outcomes in gestational diabetes treated with glibenclamide. 278 pregnant women with singleton pregnancies and no history of diabetes, at 33 -11 weeks of gestation will be enrolled and randomly assigned to two groups and 139 eligible women in any glibenclamide and insulin groups. Exclusion criteria included cardiovascular disease, hematological disease, renal or liver disease, severe infectious disease, acute respiratory failure and premature rupture of membrane. Patients will take glibenclamide or routine treatment (insulin) to level of fasting blood glucose and two hours after meals reach less than 90 and 120 respectively. After sampling, fetal Apgar at 1 and 5 minutes, percentile of newborn birth weight, blood sugar three hours after birth, calcium, incidence of hyperbilirubinemia, macrosomia, intrauterine growth restriction, shoulder dystocia, perinatal mortality and morbidity, respiratory distress, need to be admitted to the neonatal intensive care unit in new born, preeclampsia, birth trauma and hypoglycaemia in women will be compared in insulin and glibenclamide intervention group by statistical analysis techniques.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102315045N2**
Registration date: **2014-04-19, 1393/01/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-19, 1393/01/30

Registrant information

Name
Tayebe Ghasemi
Name of organization / entity
University of Medical sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Voice Chancellor for Research, Kashan University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of glibenclamide in women with gestational diabetes on maternal and neonatal outcomes

Public title

Glibenclamide effect on maternal and neonatal outcomes in women with gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female age between 18 to 45 years;

singleton pregnancy; no history of diabetes before pregnancy; gestational age between 11-33 weeks Exclusion criteria: premature rupture of membrane; severe infectious diseases; cardiovascular diseases; acute respiratory failure; hematological disease; renal disease; liver disease

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

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **278**

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
Kashan University of Medical Sciences, vice chancellor for reaserch

Street address
5th of Qotb5th of Qotb –e Ravandi Blvd., Kashan, IRAN

City
Kashan

Postal code
8715988141

Approval date
2013-08-26, 1392/06/04

Ethics committee reference number
29/5/2065/پ

Health conditions studied

1

Description of health condition studied
Gestational diabet

ICD-10 code
024.9

ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description
Birth Mother Trauma

Timepoint
Immediately after delivery

Method of measurement
Observation

2

Description
Fetal anomaly

Timepoint
Immediately after delivery

Method of measurement
Observation

3

Description
APGAR score

Timepoint
APGAR score 1and 5 minute after birth

Method of measurement
Observation and examination

4

Description
Birthweight and birthweight percentiles

Timepoint
Immediately after delivery

Method of measurement
Scales and calculate percentile

5

Description
Blood Sugar

Timepoint
From one half hour up to 3 hours

Method of measurement
Blood test

6

Description
Blood calcium

Timepoint
One week after birth

Method of measurement
Blood test

7

Description
Neonatal icterus

Timepoint

One week after birth

Method of measurement

Blood sugar

8

Description

Shoulder dystocia

Timepoint

In the delivery room

Method of measurement

Observation

9

Description

Perinatal death

Timepoint

From the second half of gestation to 28 days after birth

Method of measurement

Follow the samples and study their documents

10

Description

Respiratory distress

Timepoint

Immediately to 4 hours after birth

Method of measurement

Observation and examination of newborn

11

Description

Method of delivery

Timepoint

Date of Birth

Method of measurement

Observation

12

Description

Birth Mother Trauma

Timepoint

During and after childbirth

Method of measurement

Observation

13

Description

Maternal hypoglycemia

Timepoint

Once every three days until it becomes normal and then 4 times a day every week until delivery

Method of measurement

Blood glucose testing in the Shabih Khani hospital laboratory

14

Description

Preeclapsia

Timepoint

From the second half of pregnancy up to 24 hours after birth

Method of measurement

Blood pressure measurement, urinalysis, and clinical symptoms examination

Secondary outcomes

1

Description

Need to be admitted to the neonatal intensive care unit.

Timepoint

From birth until one week after delivery

Method of measurement

Follow up with the call and physical exam in infants hospitalized

Intervention groups

1

Description

In the glibenclamide group, patients will take 1.25 mg oral tablet glibenclamid, once daily and If need, it will increase three days to reach the maximum daily 20 mg.If glibenclamide reach to maximum dose and after 2 weeks, the blood sugar level was not normal, the patient will be treated with insulin.

Category

Treatment - Drugs

2

Description

In insulin group, treated will be start with 0.2 U/kg insulin twice daily injections subcutaneously. If needed, it will increase every 3 days to achieve normal levels of blood sugar. The patient's blood sugar will be measured 4 times daily (fasting, 2 hours after breakfast, two hours after lunch and 2 hours after dinner).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Shbih Khani Hospital

Full name of responsible person

Street address

City

Kashan

2

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person
Street address
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Kashan University of Medical Sciences and Health Service
Full name of responsible person
Dr. Gholam Ali Hamidi
Street address
5th of Qotb –e Ravandi Blvd. P.O., Kashan, IRAN
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, Kashan University of Medical Sciences and Health Service
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 University of Medical Sciences, Faculty of Medicine
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Dr.Tayebe Ghasemi
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Person responsible for scientific inquiries

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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*