

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

2014-04-19, 1393/01/30

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

Registrant information

Name

Tayebe Ghasemi

Name of organization / entity

University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

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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
Preeclampsia

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
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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

