# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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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**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* |