

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The comparative study of therapeutic effects of insulin and Glibenclamide in the gestational diabetes mellitus

#### Protocol summary

##### Summary

The purpose of this study is to compare the effects of insulin and Glibenclamide in treating gestational diabetes mellitus. A total of 88 pregnant women with gestational diabetes mellitus who came to Imam Reza hospital are recruited an 18 months study. The patients are randomly allocated into insulin or Glibenclamide group. The patients in insulin group receive 0.5 unit/kg subcutaneous insulin twice a day: 2/3 in the morning and 1/3 in the evening. Insulin dose is increased weekly if it is necessary. In Glibenclamide group, patients receive 2.5 mg oral Glibenclamide then its dose is increased 5mg per week up to getting the maximum dose of 20mg per day. Pregnant women are taught how to use the Glucometer. Their blood sugar is measured in each visit by the gynecologist weekly, as well. Primary outcome: blood glucose level. Secondary outcomes: fetal disorders such as: macrosomia, oligohydrominus, polyhydrominous, intrauterine fetal death, intrauterine retardation, fetal abnormalities, Apgar score at birth, hypoglycemia, hypocalcemia and infants bed ridden in NICU and also maternal outcomes such as cesarean section rate and pre-eclampcia

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201010203797N2**  
Registration date: **2010-12-01, 1389/09/10**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-12-01, 1389/09/10

##### Registrant information

##### Name

Maryam Zangene

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1721 4133

##### Email address

mzangene@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kermanshah University of Medical Sciences

##### Expected recruitment start date

2010-04-09, 1389/01/20

##### Expected recruitment end date

2011-09-11, 1390/06/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparative study of therapeutic effects of insulin and Glibenclamide in the gestational diabetes mellitus

##### Public title

Comparing the effects of Insulin and Glibenclamide in treating gestational diabetes mellitus

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: single pregnancy with gestational age between 11-33 weeks Exclusion criteria: patient's disagreement, multi pregnancy, history of pre-pregnancy diabetes, infectious disease, cardiovascular diseases, agglutination disorders

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **88**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Kermanshah University of Medical Sciences

**Street address**

#2 building, Kermanshah university of Medical Sciences, Shahid Beheshti Boulevard

**City**

Kermanshah

**Postal code**

6714415333

**Approval date**

2010-03-01, 1388/12/10

**Ethics committee reference number**

1/p/1.33918

**Health conditions studied****1****Description of health condition studied**

Diabetes in pregnancy

**ICD-10 code**

O24.9

**ICD-10 code description**

Diabetes mellitus in pregnancy, unspecified

**Primary outcomes****1****Description**

blood glucose level

**Timepoint**

4 times a day (being fast, 2h after breakfast, 2h after lunch, 2h after dinner

**Method of measurement**

daily recording by patient, weekly measuring in ever visit

**Secondary outcomes****1****Description**

fetal disorders such as macrosomia,

**Timepoint**

during and after birth

**Method of measurement**

laboratory works and usual tests for newborns

**2****Description**

oligohydroaminus

**Timepoint**

during and after birth

**Method of measurement**

laboratory works and usual tests for newborns

**3****Description**

determination of polyhydroaminous

**Timepoint**

during and after birth

**Method of measurement**

laboratory works and usual tests for newborns

**4****Description**

determination of intrauterine fetal death

**Timepoint**

during and after birth

**Method of measurement**

laboratory works and usual tests for newborns

**5****Description**

determination of intrauterine retardation frequency

**Timepoint**

during and after birth

**Method of measurement**

laboratory works and usual tests for newborns

**6****Description**

determination of fetal abnormalities

**Timepoint**

during and after birth

**Method of measurement**

laboratory works and usual tests for newborns

## 7

### **Description**

determination of apgar at birth

### **Timepoint**

during and after birth

### **Method of measurement**

laboratory works and usual tests for newborns

## 8

### **Description**

hypoglycemia

### **Timepoint**

during and after birth

### **Method of measurement**

laboratory works and usual tests for newborns

## 9

### **Description**

hypoglycemia

### **Timepoint**

during and after birth

### **Method of measurement**

laboratory works and usual tests for newborns

## 10

### **Description**

infants bedridden in NICU

### **Timepoint**

during and after birth

### **Method of measurement**

laboratory works and usual tests for newborns

## 11

### **Description**

cesarean section frequency

### **Timepoint**

during and after birth

### **Method of measurement**

laboratory works and usual tests for newborns

## 12

### **Description**

pre-eclampsia frequency

### **Timepoint**

during and after birth

### **Method of measurement**

laboratory works and usual tests for newborns

## **Intervention groups**

### 1

#### **Description**

Insulin (100units/ vial, Eksir co, Iran) 0.5 unit/kg subcutaneous twice a day: 2/3 in the morning and 1/3 in the evening. Insulin dose is increased weekly if it is necessary.

### **Category**

Treatment - Drugs

### 2

#### **Description**

Glibenclamid (tablet 5mg, Kimia Daroo, Iran), 2.5 mg oral then its dose is increased 5mg per week up to getting the maximum dose of 20mg per day

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza Hospital

##### **Full name of responsible person**

Dr. Maryam Zangeneh

##### **Street address**

#2 building, Kermanshah university of Medical Sciences, Shahid Beheshti Boulevard

##### **City**

Kermanshah

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kermanshah university of Medical Sciences

##### **Full name of responsible person**

Dr. Farid Najafi

##### **Street address**

#2 building, Kermanshah university of Medical Sciences, Shahid Beheshti

##### **City**

Kermanshah

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Kermanshah university of Medical Sciences

#### **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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Maryam Zangeneh

**Position**

Assistant professor/ gynecologist

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

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## Person responsible for scientific inquiries

### Contact

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Dr. Maryam Zangeneh

**Position**

Assistant professor/ gynecologist

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Kermanshah

**Postal code****Phone**

+98 84 1433 4157

**Fax**

## 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*