Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Maryam Zangene
Name of organization / entity
Kermanshah University of Medical Sciences
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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
hypoglylcemia
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-eclampcia 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

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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