Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

A randomized clinical trial on comparison of efficacy of Glibanclamide and insulin on Gestational Diabetes and outcome of pregnancy

Protocol summary

Summary

Objective: In this randomized clinical trial the efficacy of Glibenclamide and Insulin was compared on Gestational Diabetes and outcome of pregnancy. Design and setting: In this study 80 pregnant women were recruited 40 patients (group A) will be received Insulin and 40 patients (group B) will be on Glibenclamide starting with lowest requiring does and will be increased weekly till reaching 15 mg. This study are single blind and random. Participants and intervention: Inclusion criteria: Maternal age 20-40 years old; singleton pregnancy; gestational age and diagnosis of gestational diabetes will be given during pregnancy; healthy mothers with no renal diseases liver diseases and overt diabetes. Exclusion criteria: If the blood glucose is not controlled by the does of 15 mg Glibanclamid they will be shifted to Insulin and will be excluded the study. The primary outcome is to maintain (FBS) Fasting Blood glucose <95 mg/dl and 2 hour post prandial >120 mg/dl and intervention was about 14 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041317827N1**
Registration date: **2016-04-13, 1395/01/25**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2016-04-13, 1395/01/25

Registrant information

Name

Nasrin Asadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Not enough for processing

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2006-01-21, 1384/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial on comparison of efficacy of Glibanclamide and insulin on Gestational Diabetes and outcome of pregnancy

Public title

Efficacy of Glibanclamide on Gestational diabetes and outcome of pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Maternal age 20-40 years old; singleton pregnancy; gestational age and diagnosis of gestational diabetes will be given during pregnancy; healthy mothers with no renal diseases liver diseases and overt diabetes. Exclusion criteria: If the blood glucose is not controlled by the does of 15 mg glibanclamid they will be

shifted to Insulin and will be excluded the study.

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Ethics Cmmittee of Shiraz University of Medical Sciences

Street address
Zand Avenue

City
Shiraz

Postal code

Approval date
2014-02-24, 1392/12/05

Ethics committee reference number
CT-P-92-6115

Health conditions studied

1

Description of health condition studied
Gestational Diabetes

ICD-10 code
Z35.-

ICD-10 code description
high-risk pregnancy

Primary outcomes

1

Description
FBS & 2hpp

Timepoint
4 time per day: over night fast and 2 hour post parandial diet (braekfast, lunch and dinner)

Method of measurement
will be measured once a week by obestricians and twice weekly by the patients at home using Glucometer

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Insulin will be started , if FBS or 2hpp glucose levels are not control (FBS>95/dl and 2hpp>120mg/dl) respectively by diet control and exercise. 40 patient (group A) will be received Insulin (NPH or regular or both). The starting dose of Insulin is according to mean of their blood glucose.

Category
Treatment - Drugs

2

Description
Intervention group: 40 patients (group B) will be Glibenclamide starting with lowest requiring dose 1.25 mg (1/4 tab 5 mg) and will be increased by 1.5-2.50 mg weekly till reaching 15 mg.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Maternal Fetal Medicine Research Center

Full name of responsible person
Nasrin Asadi

Street address
Zand Avenue

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor Of Research, Shiraz University of Medical Sciences

Full name of responsible person
Seyed Basir Hashemi

Street address
Zand Avenue

City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor Of Research, Shiraz 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

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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