Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparsion of Gliburide and Insulin in Women With Gestational Diabetes Mellitus and Associated perinatal Outcome

Protocol summary

Summary

Women with GDM requiring pharmacological therapy were offered a choice of insulin or glibenclamide. Maternal and fetal outcomes were assessed in women treated with insulin or glibenclamide. The association among glyburide dose, severity of GDM, and selected maternal and neonatal factors was evaluated. Severity levels of GDM were stratified by fasting plasma glucose (FPG) from the oral glucose tolerance test (OGTT). Fetal outcomes included serious perinatal complications , admission to the NICU, jaundice requiring phototherapy, induction of labor, cesarean birth. Macrosomia was defined as birth weight>or =4000 g. The association between glyburide- and insulin-treated patients by severity of GDM and neonatal outcome was evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071010876N2**
Registration date: **2014-06-22, 1393/04/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-06-22, 1393/04/01

Registrant information

Name

Masumeh Mirza Moradi

Name of organization / entity

Prinatalogy department of Mahdieh hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 6263

Email address

m-bakhtiyari@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

infertility research center of Shahid Beheshti University

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparsion of Gliburide and Insulin in Women With Gestational Diabetes Mellitus and Associated perinatal Outcome

Public title

Comparsion of Gliburide and Insulin in Women With Gestational Diabetes Mellitus and Associated perinatal Outcome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : woman with singelton pregnancy who had gdm between 24 and 36 weeks who failed diet therapy Exclusion criteria: diabetes mellitus; medical complication, e.g.; hypertension or vascular disease; use of tobacco, alcohol; fetal anomaly.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

shahid beheshti university

Street address

velenjak- shahidbeheshti university

City

tehran

Postal code

Approval date

2012-02-06, 1390/11/17

Ethics committee reference number

0308/14474

Health conditions studied

1

Description of health condition studied

gestational diabet

ICD-10 code

024

ICD-10 code description

Diabetes mellitus in pregnancy

Primary outcomes

1

Description

Blood glucose

Timepoint

Daily

Method of measurement

mg / dl

Secondary outcomes

1

Description

NICU admission

Timepoint

After birth

Method of measurement

Day

2

Description

Birth weight

Timepoint

After of birth

Method of measurement

gr

3

Description

Neonatal blood glucose

Timepoint

After of birth

Method of measurement

mg/ dl

4

Description

Neonatal Bilirubin

Timepoint

After birth

Method of measurement

mg/ dl

Intervention groups

1

Description

in group of intervention glyburide the therapy is usually recommended when standard dietary management dose not consistently maintain the fasting plasma glucose at <90mg/dl or the 2-hour post prandial plasma glucose <120mg/dl. glyburide starting dose 1/25mg orally with morning meal and if necessary increase daily glyburide dose by 1/25mg Q3days in crements until maximum of 20mg /d reachd switch to insulin if 20mg /d dose not achive glucose goals those women undergo fetal testing twice weekly and serial sonography for evaluation of fetal growths.

Category

Treatment - Drugs

2

Description

in group of control insulin therapy is usually recommended when standard dietary management dose not consistently maintain the fasting plasma glucose at

<90mg/dl or the 2-hour post prandial plasma glucose <120mg/dl. a total dose of 0.4unit /kg insulin given to patient:50%NPH and 50%regular in divided dose and level of glycemic control every 2days .those women undergo fetal testing twice weekly and serial sonography for evaluation of fetal growths.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdie hospital -Shahid Beheshti University of Medical Siences

Full name of responsible person

Masoome Mirzamoradi

Street address

mahdie hospital -shoosh sq-tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

infertility research center of Shahid Beheshti University

Full name of responsible person

Dr Taheri panah

Street address

Tehran-Velenjak-Taleghani hospital

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

infertility research center of Shahid Beheshti University

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

Shahid Beheshti University of Medical Siences

Full name of responsible person

Masoome Mirzamoradi

Position

Perinatologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Masoome Mirzamoradi

Position

Perinatologist:

Other areas of specialty/work

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Person responsible for updating data

Contact

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Resident

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