Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Neonatal outcomes in women with gestational diabetes mellitus treated with metformin or insulin: a randomized clinical trial.

Protocol summary

Summary

Gestational diabetes mellitus complicates a substantial number of pregnancies. Insulin is the therapeutic agent of choice for controlling blood glucose in pregnancy.But studies have shown that metformin may have better consequences. The objective of this study was to compare maternal and neonatal outcomes in women with gestational diabetes mellitus treated with either metformin or insulin. This study used a randomized, double-blind controlled clinical trial design with two active medication conditions, which was carried out on year 2011. Subjects were chosen according to inclusion (age, gestational age, and gestational diabetes mellitus) and exclusion (contraindication for receiving metformin, history of diabetes, and serious medical condition) criteria and randomly allocated between tow groups. Metformin was started at a dose of 1000 mg daily and increased, typically over a period of two weeks, to meet glycemic targets up to a maximum daily dose of 1500 mg. Insulin was administered with an initial dose of 0.2 IU/kg/d and titrated to meet glycemic targets according to usual practice. Plasma glucose target levels were defined as fasting blood sugar (FBS) < 95 mg/dl and blood sugar (BS) 2h < 120 mg/dl. Blood sugar was recorded every two weeks up to labor time. In each visit (every two weeks) and after delivery pregnancy and neonatal outcomes in the 50 women who remained exclusively on metformin were compared with 50 women treated with insulin. The treatment was continued up to labor time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306057841N4**
Registration date: **2013-06-08, 1392/03/18**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-06-08, 1392/03/18

Registrant information

Name

Mohammad Reza Sharbafchi

Name of organization / entity

Psychiatric group, Isfahan Univercity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1222 2457

Email address

sharbafchi@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-01-01, 1389/10/11

Expected recruitment end date

2011-12-01, 1390/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Neonatal outcomes in women with gestational diabetes mellitus treated with metformin or insulin: a randomized clinical trial.

Public title

Metformin for gestational diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) 18-45 years aged; 2) pregnancy with a single fetus between 24 and 33 weeks of gestation; 3) current diagnosis of gestational diabetes mellitus according to the criteria of the Australasian Diabetes in Pregnancy Society (ADIPS); 4) no response to lifestyle modification (diet and exercise) after one week; 5) written informed consent. Exclusion criteria: 1) any contraindication for receiving metformin (renal or hepatic failure); 2) any history or documented diagnosis of diabetes prior to pregnancy; 3) history of sever drug reaction to the drugs in study; 4) any serious medical condition that may interfere with safe study participation

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: **100**

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

Isfahan University of Medical Sciences

Street address

Hezar jerib Street

City

Isfahan

Postal code

Approval date

2010-12-22, 1389/10/01

Ethics committee reference number

10/3742/د

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hyperbilirubinemia

Timepoint

During the first two hours post partum

Method of measurement

Measuring blood bilirubin

2

Description

Pregnancy Induced Hypertention

Timepoint

During pregnancy every 2 weeks

Method of measurement

Measuring blood pressure

3

Description

Neonatal hypoglycemia

Timepoint

During the first two hours post partum

Method of measurement

Measuring blood sugar

4

Description

Preterm labor

Timepoint

During pregnancy every 2 weeks

Method of measurement

Evaluating symptoms of preterm labor by physical examination and history taking

5

Description

Birtth weight

Timepoint

During the first two hours post partum

Method of measurement

Measuring Neonatal weight

6

Description

Respiratory Distress Syndrom

Timepoint

During the first two hours post partum

Method of measurement

Physical examination

Secondary outcomes

1

Description
Control of maternal hyperglycemia
Timepoint
During Pregnancy every 2 weeks
Method of measurement
Measuring fasting blood sugar and blood sugar 2h pst prandial

Intervention groups

1

Description
In metformin group, Metformin was started at a dose of 1000 mg once daily and increased, typically over a period of two weeks, to meet glycemic targets up to a maximum daily dose of 1500 mg. Plasma glucose target levels were defined as fasting blood sugar (FBS) < 95 mg/dl and blood sugar (BS) 2h < 120 mg/dl. Blood sugar was recorded every two weeks up to labor time. The treatment was continued up to labor time
Category
Treatment - Drugs

2

Description
In insulin group, insulin was administered with an initial dose of 0.2 IU/kg/d and titrated to meet glycemic targets according to usual practice. Plasma glucose target levels were defined as fasting blood sugar (FBS) < 95 mg/dl and blood sugar (BS) 2h < 120 mg/dl. Blood sugar was recorded every two weeks up to labor time. The treatment was continued up to labor time
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences, Vice-Chancellery for Research
Full name of responsible person
Dr Peyman Adibi
Street address
Hezar jerib Street
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences, Vice-Chancellery for Research
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
Isfahan University of Medical Sciences, Department of Obstetric and Gynecology
Full name of responsible person
Safie Eshaghiyan
Position
Resident of Obstetric and Gynecology
Other areas of specialty/work
Street address
Hezar jerib Street
City
Isfahan
Postal code
Phone
+998 3112367004
Fax
Email
saho5557@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences, Department of Obstetric and Gynecology
Full name of responsible person
Safura Ruholamin
Position
Obstetric and Gynecology Specialist, Assistant Professor
Other areas of specialty/work

Street address
Hezar Jerib Street
City
Isfahan
Postal code
Phone
+98 31 1236 7004
Fax
Email
s_rouholamin@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mohammad Reza Sharbafchi Zadeh
Position
Other areas of specialty/work
Street address
City
Isfahan
Postal code
Phone
Fax
Email
Sharbafchi@yahoo.com
Web page address

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