Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Pregnancy outcomes in women with gestational diabetes treated with metformin and insulin

Protocol summary

Study aim
Determination of the effect of metformin and insulin in the treatment of pregnant women with gestational diabetes

Design
Clinical trial, with randomized groups, phase 4, on 100 patients, for randomization from the table of random numbers, the sample size has been done with the help of stata11 software.

Settings and conduct
The location of the study is Shohada Tajrish Hospital, Tehran. At the beginning of the study, the variables related to the mother are measured. Then they are divided into two groups of insulin and metformin and receive the prescribed doses, and the dose is adjusted according to fasting and postprandial sugar levels. Treatment of side effects as well as therapeutic doses and prescription drugs are also recorded.

Participants/Inclusion and exclusion criteria
All participating pregnant women must have one of the following: Fasting blood glucose (92-125 mg/dl 1-hour blood glucose ≥ 180 mg/dl; 2-hour blood glucose (153-199 mg/dl) After 75 grams of oral glucose; Exclusion criteria: women for whom the use of metformin is contraindicated؛diagnosed fetal anomaly or rupture of membranes at the time of entering the study؛ and the presence of any other medical condition.

Intervention groups
Pregnant women treated with insulin and pregnant women treated with metformin

Main outcome variables
Age at termination of pregnancy؛ Birth weight Apgar 5 minutes؛ Incidence of birth defects؛ Rate of hospitalization in NICU؛ Rate of pre-eclampsia Cesarean section rate؛ dystocia of the infant's shoulder؛ Incidence of infant hypocalcemia؛ Need for phototherapy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220817055738N1**
Registration date: **2022-10-04, 1401/07/12**
Registration timing: **retrospective**

Last update: **2022-10-04, 1401/07/12**
Update count: **0**

Registration date
2022-10-04, 1401/07/12

Registrant information
Name
Golshan Noorollahi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 45 3379 0310
Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-09-22, 1399/07/01
Expected recruitment end date
2020-12-20, 1399/09/30
Actual recruitment start date
2020-09-22, 1399/07/01
Actual recruitment end date
2020-12-20, 1399/09/30
Trial completion date
2021-09-22, 1400/06/31

Scientific title

Comparison of Pregnancy outcomes in women with gestational diabetes treated with metformin and insulin

Public title

Comparison of the therapeutic effect of metformin and insulin in diabete

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Fasting blood glucose (92-125 mg/dl),, 1-hour blood glucose ≥ 180 mg/dl after 75 grams of oral glucose 2-hour blood glucose (153-199 mg/dl) after 75 grams of oral glucose

Exclusion criteria:

Women for whom metformin is contraindicated Diagnosed fetal anomaly Rupture of the fetal membrane at the time of entering the study Presence of any other medical condition

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were selected by simple random sampling method and divided into study groups using the table of random numbers.To use the table of random or random numbers, we first defined the framework of our statistical society; That is, we found out the exact number of people in the society and gave them a code or machine gun number respectively. To select sample people from the table, we randomly started from a point in the table in the row or column direction. After this, we checked the route numbers. We came across two types of numbers, one of which was smaller than the number of the studied community and the other was larger than the number of the community. We chose to consider only the smaller numbers.The selected number is actually the code of an individual from the community that is selected as a sample. We continued this work until we could choose a small number for the number of sample people. After the sample volume was completed, the sampling work was completed.

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

No 129، Golsar 2 Ave، Keshavarz Blvd، Ardabil city

City

Ardabil

Province

Ardabil

Postal code

5615616419

Approval date

2022-04-16, 1401/01/27

Ethics committee reference number

IR.SBMU.MSP.REC.1401.007

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

O24.4

ICD-10 code description

Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description

blood sugar level

Timepoint

Fasting blood sugar and postprandial blood sugar of the participants were monitored weekly. A comparison of the blood sugar level measured with a glucometer and plasma blood sugar was made to check the accuracy of the stated blood sugar level.

Method of measurement

Glucometer and plasma blood sugar

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the insulin group, if the fasting blood glucose was high, NPH insulin was prescribed at

the rate of 0.2 units per kilogram before going to bed. If the postprandial blood glucose was high, regular insulin was given before meals based on the postprandial glucose level, at a rate of 1 unit for every 10 mg/dL above target. If both fasting and postprandial glucose levels were high, a total dose of 0.7 units/kg was started. Insulin was divided into two doses, morning and evening. The morning dose of two-thirds of NPH insulin was divided into one-third as regular insulin injection before meals if necessary, and at night, one-half of NPH and one-half of regular insulin. Adjustment of insulin dose depending on capillary blood glucose level was done based on four glucose measurements during the day.

Category
Treatment - Drugs

2

Description
Intervention group: The women in the metformin group received an initial dose of 500 mg twice a day, and it was increased by 500-1000 mg every two weeks in order to achieve the target blood sugar, and up to a maximum daily dose of 2500 mg in divided doses. increased in meals. Metformin was continued until delivery. If blood sugar control was not achieved despite the maximum dose of metformin, insulin was added.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran, Shahada Tajrish Hospital

Full name of responsible person
Golshan Noorollahi

Street address
No 129، Golsar 2 Ave، Keshavarz Blvd، Ardabil City

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Behrooz Abtahi

Street address
Tehran؛ Evin؛ Shahid Shahriari Square؛ Shahid Beheshti University

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Email
pr-office@sbu.ac.ir

Web page address
https://sbu.ac.ir/web/RESVP

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Golshan Noorollahi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
Medical doctor

Other areas of specialty/work
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Person responsible for updating data

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Medical doctor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available