Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effect of metformin with insulin on maternal and neonatal outcomes in women with gestational diabetes

Protocol summary

Study aim
Determining the effect of metformin with insulin on maternal and neonatal outcomes in women with gestational diabetes

Design
A controlled, parallel-group, single-blind, randomized, phase 2-3 clinical trial on 132 patients. The random generator was used for randomization

Settings and conduct
This single-blind study will be conducted on pregnant women with gestational diabetes in Al-Zahra Hospital, Rasht, Iran. One group will be randomly prescribed metformin and the other group will be prescribed short-acting and long-acting insulin until the end of pregnancy. The patient and the attending physician are aware of the type of treatment, but the outcome assessor is unaware of the allocation of groups.

Participants/Inclusion and exclusion criteria
The inclusion criteria for the study will include all singleton pregnant women aged 20-45 with gestational diabetes after 26 weeks. The exclusion criteria for the study include overt diabetes, fasting sugar more than 120 mg/dL.

Intervention groups
In the intervention group, oral administration of metformin 500 mg tablets (Tehran Chemie Pharmaceutical co.) once a day and in the control group, subcutaneous administration of long-acting insulin (Detmir or Lumir, Novo Nordisk) at a dose of 0.5-1 unit per kilogram once at night, in patients with high fasting blood sugar and in cases of high post-meal blood sugar, administration of short-acting insulin (Aspart or Novorpid, Novo Nordisk) at a dose of 0.5-1 unit per kilogram before each meal until the end of pregnancy.

Main outcome variables
Blood sugar

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20080826001096N9**
Registration date: **2022-10-19, 1401/07/27**
Registration timing: **prospective**

Last update: **2022-10-19, 1401/07/27**
Update count: **0**

Registration date
2022-10-19, 1401/07/27

Registrant information
Name
Seyede Hajar Sharami
Name of organization / entity
Guilan University of Medical Science
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-10-22, 1401/07/30
Expected recruitment end date
2024-08-21, 1403/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of metformin with insulin on maternal and neonatal outcomes in women with gestational diabetes

Public title
Comparing the effect of metformin with insulin on gestational diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women with singletons Having gestational diabetes after 26 weeks

Exclusion criteria:
Having overt diabetes Having fasting sugar more than 120 mg/dL Having blood sugar one hour after a meal above 200 mg/dL Having chronic diseases of the digestive system Having a contraindication use for metformin

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **132**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research, random sequences will be generated using the Random generator program. Based on the method of random blocks and considering blocks of four, 33 blocks will be produced for 132 patients. After generating the list, each person will be assigned a unique code and will be identified with this code during the study. Allocation concealment will be done using sealed envelopes (SNOSE). Based on the size of the research sample, several aluminum envelopes will be prepared and each of the randomly generated sequences will be recorded on a card and the cards will be placed in the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes will be numbered in the same order. Finally, the lid of the envelopes will be glued and will be placed in a box respectively. At the start of the intervention, the envelopes are opened in order and the assigned group of that participant is revealed.

Blinding (investigator's opinion)
Single blinded

Blinding description
People evaluating the outcome (evaluators) and analyzing the results do not know the type of treatment assigned to the patient. In fact, the data analysis will be done by a statistics and epidemiology expert, without knowing what treatment the patients in group A and B have received. Also, a gynecology resident (outcome assessor) will measure and record the primary and secondary outcomes of patients in both groups without knowing that patient has received metformin or insulin treatment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences

Street address
Research and Technology Vice-Chancellor of Gilan University of Medical Sciences., Namjoo St

City
Rasht

Province
Guilan

Postal code
41446-66949

Approval date
2022-06-29, 1401/04/08

Ethics committee reference number
IR.GUMS.REC.1401.177

Health conditions studied

1

Description of health condition studied
Diabetes mellitus in pregnancy

ICD-10 code
O24.9

ICD-10 code description
Unspecified diabetes mellitus in pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Blood sugar

Timepoint
Fasting before the intervention and one hour after the intervention weekly until the end of pregnancy

Method of measurement
Glucometer

Secondary outcomes

1

Description
Maternal hypoglycemic episodes
Timepoint
Fasting before the intervention and one hour after the intervention weekly until the end of pregnancy
Method of measurement
Glucometer

2

Description
Blood pressure disorders in pregnancy
Timepoint
Monthly visit after the start of the intervention
Method of measurement
Sphygmomanometer

3

Description
Preterm delivery
Timepoint
Postpartum
Method of measurement
Delivery earlier than 37 weeks of pregnancy

4

Description
Intrauterine fetal death
Timepoint
Weekly visit after the start of the intervention
Method of measurement
Absence of fetal heartbeat in ultrasound

5

Description
Polyhydramnios
Timepoint
Weekly visit after the start of the intervention
Method of measurement
Sonography

6

Description
Macrosomia
Timepoint
Postpartum
Method of measurement
scales

7

Description
Nneonatal hypoglycemia
Timepoint
After birth
Method of measurement
Bleeding of the heel

8

Description
Shoulder dystocia
Timepoint
During childbirth
Method of measurement
Observation

9

Description
Respiratory distress syndrome
Timepoint
Weekly visit after the start of the intervention
Method of measurement
Neonatal specialist report

10

Description
Need for Neonatal Intensive Care Unit
Timepoint
After birth
Method of measurement
Neonatal specialist report

11

Description
Metformin side effects
Timepoint
Immediately after intervention and weekly follow-up
Method of measurement
Patient report

Intervention groups

1

Description
Intervention group: Administration of oral metformin 500 mg tablets (Tehran Chemie Pharmaceutical co.) once a day until the end of pregnancy
Category
Treatment - Drugs

2

Description
Control group: Subcutaneous administration of long-acting insulin (Detmir or Lumir, Novo Nordisk) at a dose of 0.5-1 unit per kilogram once at night, in patients with high fasting blood sugar and in cases of high post-meal blood sugar, administration of short-acting insulin (Aspart or Novorpid, Novo Nordisk) at a dose of 0.5-1 unit per kilogram before each meal until the end of pregnancy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Seyedeh Hajar Sharami
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Seyedeh Hajar Sharami
Position
Professor
Latest degree
Specialist
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Signing a contract between two parties
From where data/document is obtainable
Dr. Seyedah Hajar Sharmi sharami@gums.ac.ir
What processes are involved for a request to access data/document
After contacting Dr. Sharami via email or phone call, and if possible, a face-to-face meeting, and after the contract is signed, the data will be available.
Comments