Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the efficacy of two treatment regimens of metformin and insulin therapy for diabetes on results of glucose tolerance test after delivery in women with gestational diabetes

Protocol summary

Study aim
Comparing of the effects of two regimens of metformin and insulin therapy on the results of postpartum glucose tolerance test in pregnant women with gestational diabetes mellitus

Design
Clinical trial, double blinded, randomized, parallel, with 60 patients

Settings and conduct
In this study, all pregnant women with a diagnosis of gestational diabetes who are referred to the midwifery clinic of Sayyad Shirazi hospital in Gorgan in order to continue their post-natal care will be considered as a statistical society, among which A randomized sample of 60 pregnant mothers with inclusion criteria and without exclusion will be included in the study

Participants/Inclusion and exclusion criteria
Criteria for inclusion: Includes single-pregnancy Gestational age 20 to 34 weeks Diet and exercise tratment for at least a week without blood sugar control absence of risk factors for lactic acidosis and absence of anatomical and chromosomal anomalies. FBS more than 126 mg / dL , HbA1C levels greater than 6.5% exclusion criteria: Diagnosis of pre-pregnancy diabetes, Dissatisfied to cooperate in the study, presence of metabolic disorders in the patient Need to change treatment from metformin to insulin during the study

Intervention groups
1) Insulin treatment group 2) Metformin treatment group

Main outcome variables
results of glucose tolerance test after delivery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180103038196N5**
Registration date: **2018-07-31, 1397/05/09**
Registration timing: **retrospective**

Last update: **2018-07-31, 1397/05/09**
Update count: **0**

Registration date
2018-07-31, 1397/05/09

Registrant information

Name
Amir Hossein Salimi Kordasiabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-31, 1397/03/10

Expected recruitment end date
2018-07-22, 1397/04/31

Actual recruitment start date
2018-05-31, 1397/03/10

Actual recruitment end date
2018-07-22, 1397/04/31

Trial completion date
empty

Scientific title
Comparison of the efficacy of two treatment regimens of metformin and insulin therapy for diabetes on results of glucose tolerance test after delivery in women with

gestational diabetes

Public title
Comparison of the effect of two regimens of metformin and insulin on results of postpartum glucose tolerance test

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Single pregnancy pregnancy Gestational age 20 to 34 weeks Diet and exercise treatment for at least a week without blood glucose control absence of risk factors for lactic acidosis and the absence of anatomical and chromosomal abnormalities fasting blood sugar greater than or equal to 126 mg / dl , HbA1C levels greater than 6.5%

Exclusion criteria:
Diagnosis of pre-pregnancy diabetes, presence of metabolic disorders in the patient Need to start treatment with insulin in oral treatment patients The lower limit of fasting glucose is 92 mg / dL and glucose levels will start for insulin patients two hours after meals, if treatment with metformin is higher than 120. Dissatisfied to cooperate in the study metabolic disorder in the patient

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The blocked random allocation method will be used. Thus, for example, a type of treatment is given to the first block and the other to the second, and again to the first block to the third block, and so on.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is a double-blind, so that the patient and the person providing the medication to the patient and the person analyzing the data do not know the type of treatment used for each person.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of gorgan University of Medical Sciences

Street address
Golestan university of medical science ,Beginin of Shastkola Street, 5th Kilometers of Gorgan Sari Road, Gorgan

City
Gorgan

Province
Golestan

Postal code
4934174515

Approval date
2018-05-30, 1397/03/09

Ethics committee reference number
IR.Gomus.REC.1397.028

Health conditions studied

1

Description of health condition studied
Gestational Diabetes

ICD-10 code
O24.4

ICD-10 code description
Gestational diabetes mellitus

Primary outcomes

1

Description
Control of serum glucose level in pregnant women with gestational diabetes mellitus

Timepoint
4 days and 6 weeks after delivery

Method of measurement
Oral Glucose Tolerance Test and HbA1C Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group 1: Insulin therapy

Category
Treatment - Drugs

2

Description
Intervention group: Group 2: Treatment with metformin
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sayyad Shirazi Hospital
Full name of responsible person
Dr. Moghadaseh Jahanshahi
Street address
Sayyad Shirazi Hospital, Sayyad Shirazi Blv, Gorgan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Moghadaseh Jahanshahi
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Golestan university of medical science ,Beginin of Shastkola Street, 5th Kilometers of Gorgan Sari Road, Gorgan
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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
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Moghadaseh Jahanshahi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact

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Gorgan University of Medical Sciences

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Dr. Amir Hossein Salimi kord asiabi

Position
General practitioner

Latest degree
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Other areas of specialty/work
General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
Data is potentially are obtainable after unidentifiable individuals

When the data will become available and for how long
Start the access after 6 months after establishing the results

To whom data/document is available
Professors and medical students

Under which criteria data/document could be used
It does not matter

From where data/document is obtainable
Send email to salimia92@gmail.com

What processes are involved for a request to access data/document
Using email

Comments
no