Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing of the effectiveness of insulin and metformin in treating gestational diabetes

Protocol summary

Summary

This clinical trial study will be conducted in 2013-14 aiming to use metformin to compare it with insulin in treating gestational diabetes. The sample will consist of 400 participants. Inclusion criteria: age ranging from 18 to 45; affliction with gestational diabetes; pregnancy with a single embryo; pregnancy for 20 weeks or longer; and meeting the hospital's common criteria concerning the beginning of insulin treatment. Exclusion criteria: diagnosis with pre-pregnancy diabetes; metformin consumption; embryonic anomaly; hypertensive pregnancy disorders; pre-eclampsia; embryonic growth restriction; premature rupture; liver disorders or kidney disorders during the treatment period. By single blinding for patient and simple randomization, the participants will be divided in 2 groups of 200, treated by either metformin or insulin. On the first day, 500 mg to 2 g of metformin will be applied once or twice a day and this amount would be increased for two weeks so that the target blood glucose could reach the maximum 2500 mg. As for insulin, according to the hospital's common method, it will be used in a .5 to 1 unit/kg dosage dependent on the pregnancy age (in the 1st 3 months: .5 unit/kg, 2nd 3 months: .7 unit/kg and the 3rd 3 months:1 unit/kg). According to the Multiday injection rule, we will start with N.P.H and Regular insulin. Mother's blood glucose, side effects in the baby and baby's growth will be controlled via phone every 6 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010116025N1**
Registration date: **2014-05-18, 1393/02/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-18, 1393/02/28

Registrant information

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Payam Sadeghi
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Hormozgan University of Medical Sciences

Expected recruitment start date

2014-01-28, 1392/11/08

Expected recruitment end date

2014-08-21, 1393/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of the effectiveness of insulin and metformin in treating gestational diabetes

Public title

Metformin is more effective than insulin in treating gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age ranging from 18 to 45; affliction with gestational diabetes according to the criteria pinpointed by Australian Diabetes in Pregnancy Society (ADIPS); pregnancy with a single embryo; 20th to 32th week of pregnancy; meeting the hospital's common criteria concerning the beginning of insulin (after the diet intervention and physical exercises their capillary blood glucose after an overnight fast should be above 90 mg/dl or their 2hpp blood glucose measurement should be above 120.6 d.l.). Exclusion criteria: pre-pregnancy diabetes; metformin consumption; embryonic anomaly; hypertensive pregnancy disorders; pre-eclampsia; embryonic growth restriction and premature rupture.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **400**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hormozgan University of Medical Sciences
Street address
The eastern side of Shahid Mohammadi hospital, Jomhouri Eslami Blvd
City
Bandar Abbas
Postal code
Approval date
2013-07-16, 1392/04/25
Ethics committee reference number
HEC-92-4-25-2

Health conditions studied

1

Description of health condition studied
gestational diabetes
ICD-10 code
O24.9
ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description
Maternal blood glucose control
Timepoint
During pregnancy: every 2 weeks
Method of measurement
During pregnancy: every 2 weeks

Secondary outcomes

1

Description
Birth weight
Timepoint
2 hour after delivery
Method of measurement
Neonatal weight measurement

2

Description
Birth height
Timepoint
2 hour after delivery
Method of measurement
Baby Height gauges

3

Description
Head circumference
Timepoint
2 hour after delivery
Method of measurement
With using meter

4

Description
Chest circumference
Timepoint
2 hour after delivery
Method of measurement
With using meter

5

Description
First minute apgar
Timepoint

One minute after delivery
Method of measurement
Apgar score

6

Description
Fiftt minute apgar
Timepoint
Five minutes after delivery
Method of measurement
Apgar score

Intervention groups

1

Description
In the metformin group, the treatment will begin with 500 mg of metformin (produced by Apotex company, holding the trademark; Apo Metfromin). It will be given once or twice a day starting with meals so that within a 1 to 2 week's time the target blood glucose is reached or to the maximum level of 2500 mg of daily dosage it will be increased. In case the treatment target is not reached through the mere consumption of metformin, three weeks (on average) after the beginning of metformin treatment, insulin will be added. If taking metformin is inhibited for the mother (if she suffers from some sort of liver, kidney disorder or sepsis) or detect intra uterin growth retardation stop the use of metformin.
Category
Treatment - Drugs

2

Description
Insulin will be used in a 0.5 to 1 unit/kg dosage dependent on the pregnancy age (in the 1st trimester: 0.5 unit/kg, 2nd trimester: 0.7 unit/kg and the 3rd trimester: 1 unit/kg). According to the Multi day injection rule, we will start with NPH and regular insulin
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital- Bandar Abbas
Full name of responsible person
Dr. Mojgan Rahbar
Street address
City
Bandar Abbas

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology, Hormozgan University of Medical Sciences
Full name of responsible person
Dr. Abdolazim Nejatizadeh
Street address
Shahid Mohammadi
City
Bandar Abbas
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research and Technology, Hormozgan University of Medical Sciences
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
Hormozgan University of Medical Sciences
Full name of responsible person
Dr. Mojgan Rahbar
Position
Assistant of Obstetrics and Gynecology
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Person responsible for scientific inquiries

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Name of organization / entity
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Dr. Mojgan Rahbar

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Person responsible for updating data

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Payam Sadeghi
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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