Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of pregnancy outcome and glycemic control between insulin versus insulin plus metformin in management of gestational diabetes.

Protocol summary

Study aim
Comparison of pregnancy outcome and glycemic control between insulin versus insulin plus metformin in management of gestational diabetes

Design
In this randomized clinical trial, 60 patients with GDM were enrolled. Patients were divided into 2 groups. In the first group, with 20 patients, if despite insulin proper diet, FBS is still above 100, metformin begins. In the second group with 40 patients, if FBS is high, insulin dose is increased and metformin is not given.

Settings and conduct
In this study, all pregnant women with a diagnosis of gestational diabetes who are referred to the midwifery clinic of Shiraz University of medical sciences 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
Inclusion criteria: Single-pregnancy pregnancy Gestational age 20-34 weeks FBS is higher than 100 mg/dL, Age range 18 to 40 years. Exclusion criteria: Diagnosis of pre-pregnancy diabetes, presence of metabolic disorders in the patient Need to start treatment with insulin in oral treatment patients, dissatisfied to cooperate in the study, metabolic disorder in the patient, Gestational Hypertension .

Intervention groups
In the first group, with 40 patients, if despite insulin proper diet, FBS is still above 100, metformin begins. In the second group with 40 patients, if FBS is high, insulin dose is increased and metformin is not given.

Main outcome variables
Results of glucose tolerance test after delivery

General information

Reason for update
sample size

Acronym

IRCT registration information
IRCT registration number: **IRCT20140317017035N5**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **retrospective**

Last update: **2020-05-13, 1399/02/24**
Update count: **1**

Registration date
2020-05-04, 1399/02/15

Registrant information

Name
Maryam Kasraeian

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 23 32365

Email address
kasraeem@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-09, 1397/04/18

Expected recruitment end date
2018-09-21, 1397/06/30

Actual recruitment start date
2018-07-09, 1397/04/18

Actual recruitment end date
2018-09-21, 1397/06/30

Trial completion date
2018-09-21, 1397/06/30

Scientific title
Comparison of pregnancy outcome and glycemic control

between insulin versus insulin plus metformin in management of gestational diabetes.

Public title
Comparison of the effect of two regimens of metformin and insulin on glucose tolerance test
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Single-pregnancy Gestational age 20-34 weeks FBS is higher than 100 mg/dL Age range 18 to 40 years
Exclusion criteria:
Diagnosis of pre-pregnancy diabetes, presence of metabolic disorders in the patient Need to start treatment with insulin in oral treatment patients Dissatisfied to cooperate in the study Metabolic disorder in the patient Gestational Hypertension
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software Minitab; Sequence Building: Using randomized 4 in 4 blocks; Hiding method: Use similar pocket
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 Cmmittee of Shiraz University of Medical Sciences
Street address
Headquarters Of Shiraz University of Medical Sciences, Zand St, Shiraz
City
Shiraz
Province
Fars
Postal code
34786-71946
Approval date
2018-07-07, 1397/04/16
Ethics committee reference number
IR.SUMS.MED.REC.1397.167

Health conditions studied

1

Description of health condition studied
Gestational Diabetes
ICD-10 code
O24.41
ICD-10 code description
Gestational diabetes mellitus in pregnancy

Primary outcomes

1

Description
Control of serum glucose level in pregnant women with gestational diabetes mellitus
Timepoint
On average checked twice at week 36
Method of measurement
Oral Glucose Tolerance Test

2

Description
Blood sugar levels
Timepoint
1 hour after birth
Method of measurement
Glucometer

Secondary outcomes

1

Description
Neonate weight
Timepoint
After birth
Method of measurement
scale

2

Description
Apgar score
Timepoint
First and fifth minutes after birth
Method of measurement
Apgar score scale

Intervention groups

1

Description
Intervention group: In first group of intervention, if the blood suger is not controlled with diet. Initially, insulin will be started at 0.5_1 unit per kg, and then if it need, more glucophage (Actoverco factory) and insulin detemir will be added intermittently . The maximum dose of glucophage is up to 2000 mg. changes in oral and injectable medication will be continued for up to 36 weeks in permited manner, if its necessary . To minimize the hypoglycemic effect in infants the glucophage will reduce by one every 4 days from week 36 onwards.
Category
Treatment - Drugs

2

Description
Control group: In group two of intervention, if the blood suger is not controlled with diet. Initially, insulin will be started at 0.5_1 unit per kg, and then if it need, more insulin detemir will be added intermittently.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez hospital of Shiraz University of Medical Sciences
Full name of responsible person
Azadeh Ghahartras
Street address
Hafez Hospital; Shahid Chamran blvd
City
Shiraz
Province
Fars
Postal code
34786-71946
Phone
+98 71 3612 8257
Email
hafez_perina@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Yoones Ghasemi
Street address
Building of Shiraz University of Medical Sciences, Zand Ave
City
Shiraz
Province
Fars
Postal code
34786-71946
Phone
+98 71 3235 7282
Email
ghasemiy@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Azadeh Ghahartars
Position
Resident of obstetrics and gynecology
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code

34786-71946

Phone
+98 71 3233 2365

Email
Hafez_perina@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Maryam Kasraeian

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Maternal- Fetal Medicine (Perinatology), Hafez Hospital, Chamran Ave., Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3612 8258

Email
maryamkasraeian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Maryam Kasreian

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Maternal- Fetal Medicine (Perinatology), Hafez Hospital, Chamran Ave., Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
34786-71946

Phone
+98 71 3612 8257

Email
maryamkasraeian@gmail.com

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
Not applicable

Informed Consent Form
Yes - There is 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
IPD: Information and research data Ethic form: Complete the Ethic form by the patient

When the data will become available and for how long
IPD: 2019 Ethic form: 2019

To whom data/document is available
IPD: Researcher & Patient Ethic form: Patient

Under which criteria data/document could be used
IPD: Ethic form: Awareness of test results

From where data/document is obtainable
IPD: OB & Gyn ward Shiraz university of medical sciences Ethic form: OB & Gyn ward Shiraz university of medical sciences

What processes are involved for a request to access data/document
IPD: Vice chancellery Ethic form: Vice chancellery

Comments