

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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)

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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	
<u>1</u>	
Ethics committee	

Name of ethics committee	Ethics Committee 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	
<u>1</u>	
Description of health condition studied	Gestational Diabetes
ICD-10 code	O24.41
ICD-10 code description	Gestational diabetes mellitus in pregnancy
Primary outcomes	
<u>1</u>	
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
<u>2</u>	
Description	Blood sugar levels
Timepoint	1 hour after birth
Method of measurement	Glucometer
Secondary outcomes	
<u>1</u>	
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 sugar 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 permitted 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 sugar 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 Ghahartars

Street address

Hafez Hospital; Shahid Chamran blvd

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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

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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

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

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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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Maryam Kasraeian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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

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 chancellor Ethic form: Vice chancellor

Comments