

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

A clinical trial: Comparison of two insulin increasement methods in control of blood glucose in pregnant women with diagnosed diabetes on insulin therapy after betamethasone administration due to threatened preterm labor entering Mahdie hospital between 2021-2022: sliding method with increasing patient's baseline insulin method

Protocol summary

Study aim

Average blood sugar in participants after betamethasone treatment in both groups Comparison of increased units of insulin in both groups Comparing blood sugar control in both groups Comparing maternal hypoglycemia episodes in two groups Comparing number of diabetic ketoacidosis mothers in both group

Design

A parallel double blind randomized clinical trial, phase 2 that is enrolled for 34 pregnant patients who are diabetic and on insulin therapy. For randomization we use block randomization.

Settings and conduct

Study is conducted on insulin-treated diabetic pregnant women who enter and admit in Mahdie hospital with preterm labor and receive betamethasone, insulin dose regulation is done with either sliding or base adjustment method.

Participants/Inclusion and exclusion criteria

Gestational age between 24 to 34 weeks/ Gestational diabetes or Diabetes type 1 or 2 on insulin therapy/ completely controlled blood sugar before entrance to trial/corticosteroid therapy before labor Exclusion criteria: patient unwilling to continue the study or admission in our hospital.

Intervention groups

After betamethasone injection, people will be divided in two groups randomly, to the first group, Basal long acting insulin will be increased by 20%, 30%, 30%, 20% and 10% respectively and blood sugar chart is as Fasting blood sugar, premeal and 1 hour post prandial and at 12 and 3 am. For the control group, insulin therapy will continue like before but blood sugar is charted hourly after 12 hours of betamethasone injection. Urinary

ketone is assayed daily and if blood sugar is above 180, another urine sample is assayed and recorded. Average blood sugar of each person and extra insulins are recorded.

Main outcome variables

Patients blood sugar/ increase insulin dosage in both groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220215054031N1**

Registration date: **2022-04-14, 1401/01/25**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-14, 1401/01/25**

Update count: **0**

Registration date

2022-04-14, 1401/01/25

Registrant information

Name

Fateme Samadi Nasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6615 9710

Email address

faf.samadinasab@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-14, 1401/01/25

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

2022-04-14, 1401/01/25

Actual recruitment end date

2022-07-22, 1401/04/31

Trial completion date

2022-07-24, 1401/05/02

Scientific title

A clinical trial: Comparison of two insulin increasement methods in control of blood glucose in pregnant women with diagnosed diabetes on insulin therapy after betamethasone administration due to threatened preterm labor entering Mahdie hospital between 2021-2022: sliding method with increasing patient's baseline insulin method

Public title

Insulin treatment method after corticosteroid treatment in preterm labor

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age between 24 to 34 weeks Gestational diabetes on insulin therapy Diabetes type 1 or 2 on insulin therapy Completely controlled blood sugar before entrance to trial Corticosteroid therapy before labor Multiple pregnancy

Exclusion criteria:

Patients unwilling to enter or continue the study Patient refusing admission in our hospital

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **34**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization Permuted: Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. Blocking is done in two ways: In the first method, the size of all blocks is equal (for example, in a two-group experiment, 8 blocks consist of 4 participants in the intervention group and 4

participants in the control group). In the second method, the size of all blocks is randomly selected (for example, blocks of 8, 6, 10, and 14 in which there are equal numbers of each group in each block). One of the potential problems in the blockchain method is the disclosure of the last allocation in each block. This problem occurs when the study uses the block-blocking method with fixed blocks and also does not use blinding. For example, in blocks of 4, where two allocations to the intervention group and two allocations to the control group are considered, the last allocation will be predictable when the first three allocations are revealed during sampling. Of course, this problem will be solved by randomly selecting the size of the blocks. For example, Hollingworth et al. Used random blocks 2, 4, or 6 for blocking, while Wong et al. Used only 6 blocks in their study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind, and the patient and the nurse who injects the patient with insulin are unaware of which group the patient belongs to. Written consent will be obtained from all patients to participate in the study. Patients are then divided into two random groups and will not be informed which group they are in. Given that the medication received by the patient in the two groups will not change from before and only the insulin dose adjustment is different in the two study groups, the patient is aware that his blood sugar will be controlled with insulin (the patient has already used insulin to control blood sugar). However, the dose of insulin received and the method of increasing it will not be announced to them each time they receive the drug.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Koodakiar

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-02-18, 1400/11/29

Ethics committee reference number

IR.SBMU.MSP.REC.1400.745

Health conditions studied**1****Description of health condition studied**

Gestational diabetes mellitus on insulin therapy

ICD-10 code

O24.414

ICD-10 code description

Gestational diabetes mellitus in pregnancy, insulin controlled

2**Description of health condition studied**

Overt diabetes mellitus in pregnancy

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

3**Description of health condition studied**

Pre term labor

ICD-10 code

O60

ICD-10 code description

Preterm labor

Primary outcomes**1****Description**

Blood sugar of patient

Timepoint

For 5 days after betamethasone injection

Method of measurement

Glucometer with milligrams per deciliter scale

2**Description**

Hypoglycemic events

Timepoint

During 5 days after betamethasone injection

Method of measurement

Blood sugar lower than 60 mg/dl

3**Description**

Diabetic ketoacidosis: is the combination of high blood sugar and low insulin levels that cause increased ketone body products.

Timepoint

During 5 days after betamethasone injection

Method of measurement

Blood sugar with glucometer, Arterial blood gasses assays acidosis and urinary ketone assays with dipstick test

Secondary outcomes**1****Description**

Insulin units increased during 5 days

Timepoint

5 days after betamethasone injection

Method of measurement

International unit

Intervention groups**1****Description**

Intervention group: In this group we add up 20% of their basal long or intermediate acting insulin at first night after betamethasone injection, for the second and third day we add 30% to the basal insulin and 20% for the fourth day and 10% for the fifth day. Blood sugar is monitored in fasting and premeal and 1 hour after each meal and at 12 and 3 am. Based on Pre meal blood sugar level, short acting insulin is increased each time; is blood sugar is between 100-120, 1 unit is added to the short acting insulin and if blood sugar is over 120, 2 units is added per 10 mg/dl. And if blood sugar is over 140, 1 unit per 10mg/dl is added to the short acting insulin. Short acting regular insulin made in Iran, Exir company, NPH intermediate acting insulin, made in Iran, Exir company, betamethasone made in Iran, Caspian company.

Category

Treatment - Drugs

2**Description**

Control group: 12 hours after first betamethasone injection, blood sugar will be measured hourly and if it is over 120mg/dl, 1 unit of regular insulin per each 20 mg/dl blood sugar will be added to their routine insulins.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mahdie hospital

Full name of responsible person

Fateme Samadi Nasab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Dean.medicalschool@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fateme Samadi Nasab
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics

Person responsible for scientific inquiries

Contact

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Position
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All results and IPD collected for the primary outcome measure will be shared.

When the data will become available and for how long

6 month after publication

To whom data/document is available

Data is available for people working in academic institutions.

Under which criteria data/document could be used

After getting permission from the researcher, data could be used for meta-analysis.

From where data/document is obtainable

Via Fateme Samadi Nasab's Email address

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

An Email must be sent to the researcher in Persian or English and the need for data and analysis must be explained.

Comments