Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative study of intermittent dose of betamethasone, dexamethasone and daily dose of betamethasone on maternal blood sugar and fetal outcome in mothers exposed to preterm delivery

Protocol summary

Study aim

Determining and comparing the effects of intermittent doses of betamethasone, dexamethasone, and daily doses of betamethasone on maternal blood sugar and fetal outcome in mothers at risk of preterm delivery

Design

This three-arm randomized controlled clinical trial aims to compare the effects of three corticosteroid regimens on maternal blood glucose and fetal outcomes in 165 eligible pregnant women at 26–34 weeks' gestation at risk of preterm delivery. Following eligibility assessment, informed consent, and baseline data collection, participants will be allocated equally (1:1:1) to three groups of 55. Stratified randomization by gestational age will be performed using R software. Sequence generation and participant allocation will be conducted by an independent researcher.

Settings and conduct

A randomized, single-blind trial involving 165 pregnant women at risk of preterm delivery (26 and 34 weeks) is being conducted at Hajar Hospital. Participants are divided into three groups; following the acquisition of written informed consent, they remain unaware of their group assignment.

Participants/Inclusion and exclusion criteria

- Inclusion criteria: Pregnant women at risk of preterm delivery at 26–34 weeks’ gestation, with an indication for antenatal corticosteroid therapy. - Exclusion criteria: Gestational or pre-existing diabetes mellitus, use of any medication other than pregnancy supplements.

Intervention groups

The first group will receive betamethasone acetate 12 mg once daily for two days. The second group will receive betamethasone acetate 4 mg every 8 hours for six doses over two days. The third group will receive dexamethasone 6 mg every 12 hours for four doses over two days.

Main outcome variables

Maternal blood glucose following corticosteroid administration and fetal outcomes : neonatal lung maturity , NICU admission, first-minute Apgar score, and birth weight.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250502065562N1**
Registration date: **2026-11-13, 1405/08/22**
Registration timing: **prospective**

Last update: **2026-11-13, 1405/08/22**
Update count: **0**

Registration date

2026-11-13, 1405/08/22

Registrant information

Name

Fatemeh Abbasian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-21, 1405/08/30

Expected recruitment end date

2027-01-21, 1405/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of intermittent dose of betamethasone, dexamethasone and daily dose of betamethasone on maternal blood sugar and fetal outcome in mothers exposed to preterm delivery

Public title
Studying the effect of corticosteroids on preterm labor
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. Pregnant women at risk of preterm birth who are at 26-34 weeks of gestation. 2. Women who have indications for receiving corticosteroids before pregnancy. (Risk of preterm birth, short cervix, intrauterine growth retardation, twins, decreased fetal movements, antepartum hemorrhage, oligohydramnios, cholestasis, in vitro fertilization, fibroids, poor obstetric history, and Rh isoimmunization are common cases for antepartum steroid therapy.)
Exclusion criteria:
gestational diabetes or chronic diabetes use of any medication except for supplements during pregnancy, such as epilepsy or blood pressure medications.
Age
No age limit
Gender
Female

Phase
1-2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **165**
Randomization (investigator's opinion)
Randomized
Randomization description
Following verification of the inclusion and exclusion criteria and obtaining written informed consent, participants' identifying information, including their names and national identification numbers, will be coded by an independent research assistant who will not be involved in participant recruitment, administration of the therapeutic interventions, or outcome assessment. The link between participants' identities and their assigned codes will be kept confidential. Participants will then be stratified according to their gestational age at study entry into two strata: 26–30 weeks and 31–34 weeks of gestation. An independent random allocation sequence will be generated for each stratum using R software. Block randomization with variable block sizes of 3 and 6 will be employed. Block sizes will be randomly selected, such that each block of three contains one allocation to each of the three study groups, while each block of six contains two allocations to each group. The order of allocations within each block will also be determined randomly. Accordingly, participants in each stratum will be allocated to the three study groups in a 1:1:1 ratio. The random allocation sequences will be held by an independent research assistant who will not be involved in participant recruitment, administration of the therapeutic interventions, or outcome assessment. To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes will be prepared according to the randomization sequences. Following final confirmation of a participant's eligibility and acquisition of written informed consent, the envelope corresponding to the participant's gestational age stratum will be opened to reveal the assigned treatment group. The treatment allocation will be disclosed only after the participant's enrollment in the study has been formally confirmed.
Blinding (investigator's opinion)
Double blinded
Blinding description
Following the acquisition of informed consent—obtained via written forms and the provision of adequate information regarding the study objectives, study groups, and the specific intervention for each—participants are randomly assigned to study groups; however, they remain unaware of their specific group assignment. To ensure concealment, the individual responsible for randomization operates independently of the other researchers, and sealed, opaque envelopes are utilized. Consequently, the outcome assessor, the principal investigator, and the patients remain blind to the assigned group throughout the study (double-blinding).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shahrekord University of Medical Sciences
Street address
Shahrekord, Kashani Blvd., University Headquarters, Building No. 2
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Shahrekord
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Chahar-Mahal-va-Bakhtiari
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Approval date

2025-05-18, 1404/02/28

Ethics committee reference number

IR.SKUMS.MED.REC.1404.035

Health conditions studied

1

Description of health condition studied

Maternal blood sugar and fetal outcome including neonatal lung maturity, NICU admission, first-minute Apgar score, and birth weight in infants of mothers receiving corticosteroids with preterm delivery

ICD-10 code

060

ICD-10 code description

Onset (spontaneous) of labour before 37 completed weeks of gestation

Primary outcomes

1

Description

Maternal blood sugar

Timepoint

The amount of sugar in the blood, which can be measured daily as fasting sugar, immediately after corticosteroid administration for up to 2 days.

Method of measurement

Blood test

Secondary outcomes

1

Description

Infant lung maturity

Timepoint

After the baby is born

Method of measurement

Need for NICU admission due to lung immaturity

2

Description

Admission to the NICU

Timepoint

After the baby is born

Method of measurement

Need for NICU admission for a reason other than lung immaturity

3

Description

Apgar after birth

Timepoint

After the baby is born

Method of measurement

File reading

Intervention groups

1

Description

Intervention Group 1 (55 pregnant women at risk of preterm labor between 26 and 34 weeks of gestation, presenting to Hajar Hospital) receives Betamethasone acetate (Exir Pharmaceutical Company) in six 4 mg doses administered at 8-hour intervals over a period of two days.

Category

Treatment - Drugs

2

Description

Control group: (55) Pregnant women at risk of preterm labor between 26 and 34 weeks of gestation, presenting to Hajar Hospital, receive Betamethasone acetate (Exir Pharmaceutical Company) in six 4 mg doses administered at 8-hour intervals over a period of two days.

Category

Treatment - Drugs

3

Description

Second intervention group (55 pregnant women at risk of preterm labor between 26 and 34 weeks of gestation, presenting to Hajar Hospital): Participants receive four 6 mg doses of dexamethasone (Raha Pharmaceutical Company) at 12-hour intervals over a period of two days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

Sheida Shabanian

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Sponsors / Funding sources

1

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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
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medical student
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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
Undecided - It is not yet known if there will be 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
No - There is not 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
Some data such as blood sugar and fetal outcomes including NICU admission and lung maturity are shared.

When the data will become available and for how long
Access period starts 6 months after results are published.

To whom data/document is available
Researchers working in academic and scientific institutions and medical students

Under which criteria data/document could be used
The data can be used for scientific research in the pharmaceutical industry and to determine new protocols for administering corticosteroids in preterm labor. The data can also be used by academic researchers.

From where data/document is obtainable
To receive the data, individuals can send their request to Fatemeh Abbasian's Gmail address: abbasian.fa2001@gmail.com.

What processes are involved for a request to access data/document
The requests will be reviewed by me, Fatemeh Abbasian, and after verification of the applicant's individual or organization's details, the Hajar Clinical Research Center and relevant organizations at Shahrekord University of Medical Sciences will respond within a period of approximately two months.

Comments