

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of betamethasone injection on maternal and neonatal outcomes in pregnant women with gestational age 34-37 weeks exposed to preterm labor in Sayyad Shirazi Hospital, Gorgan.

Protocol summary

Study aim

The effect of betamethasone injection on maternal and neonatal outcomes in pregnant women with a gestational age of 34 to 37 weeks

Design

All mothers will be randomly divided into two groups: group A (intervention group or treatment with betamethasone) and group B (control group or normal saline injection). A randomized, double-blind, placebo-controlled clinical trial

Settings and conduct

All pregnant women with preterm labor symptoms with gestational age of 34 to the end of 36 weeks at Shahid Sayad Shirazi Hospital in Gorgan, double blind clinical trial All medical staff involved in the study will be unaware of the grouping and medication or the placebo receiving by subjects due to coding process and the similarity of the drug and placebo packages.

Participants/Inclusion and exclusion criteria

Inclusion criteria: gestational age between 34-37 weeks, preterm labor symptoms in gestational ages between 34-37 weeks , corticosteroids injection indication before childbirth according to the specialist diagnosis, consent to participate in the study exclusion criteria: intrauterine growth retardation, congenital malformation, Multiple pregnancies, placental abruption, systemic maternal diseases (diabetes, cardiovascular disease and endocrine), receiving two doses of betamethasone before the study, dissatisfaction to participate in the study

Intervention groups

Intramuscular injection of betamethasone 12 mg at 2 doses for 24 hours will be given to the intervention group and the same volume of normal saline with the same intervals to the control group.

Main outcome variables

Respiratory distress syndrome, neonatal death, need for

hospitalization in the neonatal intensive care unit, increased FBS and 2Hpp 6 weeks after delivery for mother

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191202045571N1**

Registration date: **2020-07-17, 1399/04/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-17, 1399/04/27**

Update count: **0**

Registration date

2020-07-17, 1399/04/27

Registrant information

Name

Fakhre Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3220 2565

Email address

drtaheri.f@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of betamethasone injection on maternal and neonatal outcomes in pregnant women with gestational age 34-37 weeks exposed to preterm labor in Sayyad Shirazi Hospital, Gorgan.

Public title

The effect of betamethasone injection in pregnant women exposed to preterm labor

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age 34-37 weeks, Preterm labor symptoms between the ages of 34-37 weeks gestation Need for prenatal corticosteroid injection according to specialist's diagnosis Consent to participate in the study

Exclusion criteria:

Cases of intrauterine growth retardation (IUGR) Congenital malformations Multiple pregnancies Placenta previa Maternal systemic diseases (diabetes, Cardiovascular and endocrine disease) Receiving two doses of betamethasone before study

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample sizeTarget sample size: **110****Randomization (investigator's opinion)**

Randomized

Randomization description

We use the block randomization method to randomize subjects into groups that result in equal sample sizes. We use the block size 4. From the following blocks, first select 1 by accident and divide the samples into two groups according to the order and fill the blocks A for intervention and B for placebo B A B A 2) B B A A 1) B A A B 4) A B B A 3) A A B B 6) A B A B 5)

Blinding (investigator's opinion)

Double blinded

Blinding description

The randomization process will be performed without any interference of the people who involved in the study. The drug and the placebo will be prepared in similar packages without the possibility of identification. Based on the classification, The people entered in the study will receive their own coded packages based on the specified classification, and the results will be recorded separately based on the coding on the packages and specifications of the studying groups. At the end of the study, the

analyzer will use the sample codes and coding instructions to access the nature of the groups for analysis and conclusion.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences, Gorgan, Shastkola road, Philosophical Higher Education Complex

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2019-10-20, 1398/07/28

Ethics committee reference number

IR.GOUMS.REC.1398.223

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

Preterm labor

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Incidence of diabetes and hyperglycemia in mothers

Timepoint

FBS and 2Hpp check 6 weeks after delivery for mothers and for infants up to one week later.

Method of measurement

Laboratory measurements of FBS and 2Hpp

2**Description**

incidence of respiratory distress syndrome in neonates

Timepoint

Neonatal Respiratory Distress Syndrome
Method of measurement
based on neonates clinical manifestation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A (Betamethasone Intervention) Intervention Betamethasone 12 mg(Iran Hormone production) intramuscular injection , 2 doses ,Daily

Category

Treatment - Drugs

2

Description

Control group: group B (control group or placebo), 1 cc Normal Salin (Iran Hormone production) , intramascular injection, 2 doses , daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sayyad Shirazi Hospital

Full name of responsible person

Dr. Shohreh Vosough

Street address

Philosophical Higher Education Complex, Shast Kola Road, Gorgan

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4934174515

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shohre.007@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Honarvar

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Philosophical Higher Education, Shast Kola Road, Gorgan

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Fakhre Taheri

Position

Resident

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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

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

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

It will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Use of data to complement research on the adverse effects of corticosteroids in pregnant women

From where data/document is obtainable

Contact the author of the article responsible for the research project data.

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

Contact the author of the article responsible for the research project data. Specify the type of results requested.

Comments