Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the Effect of Betamethasone on Neonatal Outcomes in Late Preterm Pregnancies

Protocol summary

Summary

Objectives: This study investigates the effect of Betamethasone on prevention of respiratory distress syndrome among neonates with gestational age of 34-36 weeks. Design: 140 pregnant women aged between 18 to 39 years who are of high risk for preterm labor in 34-36 weeks will be randomly divided into control or intervention groups (each group contains 70 participants). Setting and conduct: The intervention group and control group will receive 2 doses of 3 ml of Betamethasone and normal saline (as the placebo), respectively. Major Inclusion and Exclusion criteria: Pregnant women who are candidate for delivery in 34-36th week of gestational age with the absence of underline diseases such as diabetes or special conditions like multiple pregnancy or fetal anomalies Intervention: Receiving Betamethasone or placebo (normal saline) Main outcome measures (variables): After delivery, data including apgar score, respiratory distress syndrome and other abnormalities of the newborns will be assessed and recorded in questionnaire by neonates specialist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102919037N2**
Registration date: **2014-11-10, 1393/08/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-10, 1393/08/19

Registrant information

Name

Mahdieh Yousef-Zanjani

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6004

Email address

yusefi.mahdieh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Betamethasone on Neonatal Outcomes in Late Preterm Pregnancies

Public title

Evaluation of the Effect of Betamethasone on Neonatal Outcomes in Pregnancies

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women aged between 18 to 39 years who are candidate for delivery in 34-36th week of gestational age Exclusion criteria: Delivery after 37th week of gestational age; diabetes; fetal anomalies; delivery before receiving the two doses of the drug; multiple pregnancy

Age

From **18 years** old to **39 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Participants will be divided into two groups (control or intervention) by randomized block design

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin university of medical sciences

Street address
Shahid Bahonar Boulevard

City
Qazvin

Postal code

Approval date
2014-05-11, 1393/02/21

Ethics committee reference number
28.20.8737

Health conditions studied

1

Description of health condition studied
Respiratory Distress Syndrome of Newborn

ICD-10 code
P22.0

ICD-10 code description
Hyaline Membrane Disease

2

Description of health condition studied
Preterm Labour and Delivery

ICD-10 code
060

ICD-10 code description
Onset (Spontaneous) of Labour Before 37 Completed Weeks of Gestation

Primary outcomes

1

Description
Occurrence of respiratory distress syndrome of newborn

Timepoint
Every 30 min up to 48 h

Method of measurement
Questionnaire

2

Description
Apgar

Timepoint
At birth

Method of measurement
Checklist

Secondary outcomes

1

Description
Need for newborn admission

Timepoint
Up to 48 h

Method of measurement
Questionnaire

Intervention groups

1

Description
First intervention group: Intramuscularly injection of 6ml of betamethasone solution (4mg/ml) (devided into two 3ml injection with a 12-hour interval), from Sahaamy-e Aam drug manufacturing company, Boroujerd, Iran, registered No. 1228030994

Category
Treatment - Drugs

2

Description
Second intervention group: Intramuscularly injection of 6ml of normal saline solution (9mg/ml) (devided into two 3ml injection with a 12-hour interval), from Daroupakhsh drug manufacturing company, Tehran, Iran, registered No. 1228057458

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kosar Obstetric and Gynecology Hospital

Full name of responsible person
Dr. Ezzatossadat Haj Seyyed Javadi

Street address
Kosar Street, Ayatollah Taleghani Boulevard

City
Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Investigator

Full name of responsible person
Dr. Maryam Jafari

Street address
Kosar Hospital, Kosar Street, Ayatollah Taleghani Boulevard

City
Qazvin

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Investigator

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kosar Obstetric and Gynecology Hospital

Full name of responsible person
Dr. Maryam Jafari

Position
Gynecology Resident

Other areas of specialty/work

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Kosar Street, Ayatollah Taleghani Boulevard

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+98 28 3323 6374

Fax

Email
dr.jafari1981@gmail.com

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty