Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Corticosteroid, Antibiotic and Tocolytic in patient with PPROM (28-32 week) on neonalal outecome

Protocol summary

Summary

Aim: To determine the effect of corticosteroid, antibiotic and tocolytic in patient with PPROM on neonalal outecome . Inclusion Criteria: PPROM, gestational ages 34-28 weeks, Live fetus Exclusion criteria medical complications in the mother , abnormal fetal heart rate patterns, fetal anomalies Population: pregnant women Sample size: 64 person Intervention study: In case group received magnesium sulfate intravenously 20 percent for 48 hours. two doses of 12 mg betamethasone within 24 hours intramuscular Ampicillin 2 gr every 6 hours for 48 hours and Controls group just received Ampicillin 2 gr every 6 hours for 48 hours Time: gestational ages 34-28 weeks Primary outcomes: Upgar score

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105226558N1**
Registration date: **2011-07-07, 1390/04/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-07, 1390/04/16

Registrant information

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Name of organization / entity

Bums

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2007-06-27, 1386/04/06

Expected recruitment end date

2009-03-16, 1387/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Corticosteroid, Antibiotic and Tocolytic in patient with PPROM (28-32 week) on neonalal outecome

Public title

The Effect of Corticosteroid, Antibiotic and Tocolytic on neonalal outecome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: PPROM in gestational ages 34-28 weeks, Live fetus Exclusion criteria medical complications in the mother , imminent delivery,receiving antibiotics One week before admission to hospital or need to prescribe antibiotics after admission, , abnormal fetal heart rate patterns, fetal anomalies and other factors require termination of pregnancy and labor induction in maternal and fetal

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

birjand university of medical sience

Street address

Iran- South Khorasan- Birjand - St. Ghafari- Birjand University of Medical Sciences

City

birjand-

Postal code

Approval date

2007-06-25, 1386/04/04

Ethics committee reference number

443

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome of newborn

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Neonatal outcome

Timepoint

48h

Method of measurement

questioner

Secondary outcomes

1

Description

Apgar score

Timepoint

After Birth

Method of measurement

questioner

Intervention groups

1

Description

Magnesium sulfate intravenously 20 percent for 48 hours.

Category

Treatment - Drugs

2

Description

two doses of 12 mg betamethasone within 24 hours intramuscular

Category

Treatment - Drugs

3

Description

Ampicillin 2 gr every 6 hours for 48 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Birjand University of Medical Sience

Full name of responsible person

Street address

Iran- South Khorasa - Birjand - St. Ghafari- Birjand University of Medical Sciences

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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Birjand University of Medical Sciences, Ghafari St. , Birjand, South Khorasan

City
Birjand
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand University of Medical Sciences
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

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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