

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The Effect of Corticosteroid, Antibiotic and Tocolytic in patient with PPRM (28-32 week) on neonatal outcome

Protocol summary

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Summary

Aim: To determine the effect of corticosteroid, antibiotic and tocolytic in patient with PPRM on neonatal outcome . Inclusion Criteria: PPRM, 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

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

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

Name

Aghdas Karimi

Name of organization / entity

Bums

Country

Iran (Islamic Republic of)

Phone

+98 56 1444 0550

Email address

Scientific title

The Effect of Corticosteroid, Antibiotic and Tocolytic in patient with PPRM (28-32 week) on neonatal outcome

Public title

The Effect of Corticosteroid, Antibiotic and Tocolytic on neonatal outcome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: PPRM 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 science

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 Science

Full name of responsible person

Street address

Iran- South Khorasa - Birjand - St. Ghafari- Birjand
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mr Aahmadi

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

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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

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr Mahboobeh Zangoeei

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Assistant Professor

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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