Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The effect of prescription versus not prescription of the prophylactic antibiotic on clinical outcomes in newborn with transient tachypnea: a triple blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of prescription versus not prescription of the prophylactic antibiotic on clinical outcomes in newborn with transient tachypnea. Design: a triple blind randomized clinical trial. Setting and conduct: The eligible newborns with transient tachypnea who will hospitalized in the Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: Neonate with gestational age of 34 to 41 weeks; respiratory distress for at least 4 hours. Exclusion criteria: prenatal or perinatal infection; congenital anomalies; disposal of meconium during delivery; Apgar score of 7 or lower; pneumonia; indication of mechanical ventilation; signs of primary septicemia; need for additional oxygen with pressure more than 40%. Intervention group: Routine care plus ampicillin 25 mg/kg 3 times a day for 72 hours and amikacin 10 mg/kg 2 times a day for 72 hours Control group: Just routine care. Primary outcome: (a) assessing the incidence of pneumonia on the first, second, and third days after intervention through physical examination; (b) assessing the signs of septicemia on the first, second, and third days after intervention through physical examination; (c) assessing the incidence of death on the first, second, and third day after intervention through physical examination Secondary outcome: (a) assessing duration of hospitalization based on medical record at discharge; (b) assessing blood culture on the first, second, and third days after intervention through laboratory test; (c) assessing adverse effect of medications such as renal failure on the first, second, and third days after intervention through laboratory test. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: newborns will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609049014N114**
Registration date: **2016-09-08, 1395/06/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-08, 1395/06/18

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-09-22, 1396/06/31

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

Scientific title
The effect of prescription versus not prescription of the prophylactic antibiotic on clinical outcomes in newborn with transient tachypnea: a triple blind randomized clinical trial

Public title
The effect of prescription versus not prescription of the prophylactic antibiotic on clinical outcomes in newborn with transient tachypnea
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Neonate with gestational age of 34 to 41 weeks; respiratory distress for at least 4 hours. Exclusion criteria: prenatal or perinatal infection; congenital anomalies; disposal of meconium during delivery; Apgar score of 7 or lower; pneumonia; indication of mechanical ventilation; signs of primary septicemia; need for additional oxygen with pressure more than 40%.
Age
From **1 day** old to **7 days** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: newborns will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2016-08-06, 1395/05/16
Ethics committee reference number
IR.UMSHA.REC.1395.224

Health conditions studied

1

Description of health condition studied
Transient tachypnea
ICD-10 code
P22.1
ICD-10 code description
Transient tachypnoea of newborn

Primary outcomes

1

Description
assessing the incidence of pneumonia
Timepoint
on the first, second, and third days after intervention
Method of measurement
through physical examination

2

Description
assessing the signs of septicemia
Timepoint
on the first, second, and third days after intervention
Method of measurement
through physical examination

3

Description
assessing the incidence of death
Timepoint
on the first, second, and third day after intervention
Method of measurement
through physical examination

Secondary outcomes

1

Description
assessing duration of hospitalization
Timepoint
based on medical record
Method of measurement
at discharge

2

Description
assessing blood culture
Timepoint
on the first, second, and third days after intervention
Method of measurement
through laboratory test

3

Description
assessing adverse effect of medications such as renal failure
Timepoint
on the first, second, and third days after intervention
Method of measurement
through laboratory test

Intervention groups

1

Description
Just routine care
Category
Treatment - Other

2

Description
Routine care plus ampicillin 25 mg/kg 3 times a day for 72 hours and amikacin 10 mg/kg 2 times a day for 72 hours
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Dr Leila Bahadorbeigi
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research the Technology, Hamadan 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
Fatemieh Hospital
Full name of responsible person
Dr Leila Bahadorbeigi
Position
Pediatric Resident
Other areas of specialty/work
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan
Postal code
Phone
+98 81 3828 3939
Fax
Email
bahar_liela@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity

Fatemieh Hospital

Full name of responsible person

Dr Mohammad Kazem Sabzei

Position

Pediatrics

Other areas of specialty/work

Street address

Fatemieh Hospital, Pasdaran Ave

City

Hamadan

Postal code

Phone

+98 81 3828 3939

Fax

Email

mk_sabzehei@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax

Email

poorolajal@umsha.ac.ir

Web page address

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