

# 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 Fatemeh 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.

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Fatemieh Hospital  
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**Position**  
Pediatrics  
**Other areas of specialty/work**  
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## Person responsible for updating data

**Contact**  
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**Full name of responsible person**  
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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*