

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of salbutamol in treatment of transient tachypnea of newborn

Protocol summary

Summary

In this study we will evaluate the effect of salbutamol nebulies in improving signs of transient tachypnea of newborn . This double blind, clinical controlled trial will be done on 70 late Preterm, term, post term neonate with transient tachypnea of newborn during first six hours after birth. The diagnosis of transient tachypnea of newborn will be according to clinical evidence of tachypnea (respiratory rate greater than 60 per minute) with or without respiratory distress, with at least one sign of radiologic finding of transient tachypnea of newborn on chest X Ray. The neonates will be divided randomly in two groups, to receive one dose of Salbutamol (Asthalin manufacture by CIPLA ,INDIA) 0.15 miligram, equal to; 0.15mililiter per kilogram of body weight (solution A) or 0.15 mililiter per kilogram of body weight %0.9 normal salin solution (solution B) by nebulizer, within 10 minutes. Before and after treatment in intervals of: 30 minute, one, four, six hours, the respiratory rate, heart rate, oxygen saturation, oxygen requirement, Retraction score (base on Silverman - Anderson Retraction score) and the time of first feeding and duration of hospitalization should be evaluated and recorded. The above data will be analyzed by SPSS statistical program software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062518232N1**
Registration date: **2014-08-07, 1393/05/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-07, 1393/05/16

Registrant information

Name

Fatemeh Heydari

Name of organization / entity

Babol Medical Sciences Univercity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Babol University of Medical Sciences

Expected recruitment start date

2014-08-02, 1393/05/11

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

The effect of salbutamol in treatment of transient tachypnea of newborn

Public title

The effect of salbutamol in treatment of transient tachypnea of newborn

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The late preterm (gestational age of 34 - 37 weeks) and term (gestational age of 37 -42 weeks) and post term (gestational age greater than 42 weeks) neonates with tachypnea (Respiratory Rate greater than 60 per minute) with or without respiratory distress within

6 hours of birth. Exclusion criteria: Preterm neonates (gestational age less than 34 weeks); neonates with history of asphyxia; birth trauma; meconium aspiration syndrome; congenital pneumonia; a history of chorioamnionitis or corticosteroids therapy in mother; gross congenital anomaly and neonates with tachycardia; arrhythmia; blood culture or CRP positive during treatment will be excluded.

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

Street address

Ganjafrooze street

City

Babol

Postal code**Approval date**

2014-04-26, 1393/02/06

Ethics committee reference number

30/4026/پ / ز

Health conditions studied**1****Description of health condition studied**

Transient tachypnea of newborn

ICD-10 code

P22.1

ICD-10 code description

Transient tachypnea of newborn

Primary outcomes**1****Description**

Tachypnea

Timepoint

before intervention; 30 minute, one, four, six hours later

Method of measurement

observation and record of respiratory rate per minute

Secondary outcomes**1****Description**

Respiratory Rate

Timepoint

before intervention; 30 minute, one, four, six hours later

Method of measurement

Observation and record

2**Description**

Heart beat

Timepoint

before intervention; 30 minute, one, four, six hours later

Method of measurement

Observation and record of heart beat per minute

3**Description**

Time of start feeding

Timepoint

Before intervention; 30minute, one, four, six hours later

Method of measurement

hour

4**Description**

O2 requirement

Timepoint

Before intervention; 30 minute, one, four, six hours later

Method of measurement

per liter. per minute

5**Description**

Duration of hospitalization

Timepoint

day

Method of measurement

day

6

Description

Retraction Score

Timepoint

Before intervention ;30 minute, one, four, six hours later

Method of measurement

Observation and record on bases of SILVERMAN - ANDERSON Retraction Score

7

Description

Arterial Blood Gases

Timepoint

before intervention, and after intervention if necessary

Method of measurement

Blood sample

8

Description

Oxygen saturation percent

Timepoint

before intervention; 30 minute, one, four, six hours later

Method of measurement

observation and record of oxygen saturation (percent)

Intervention groups

1

Description

Intervention group : administration of one dose of Salbutamol (Asthalin, manufactured by CIPLA, INDIA) 0.15 milliliter per kilogram of body weight, by nebulizer within 10 minutes.

Category

Treatment - Drugs

2

Description

control group : to receive one dose of 0.15 milliliter per kilogram of body weight of 0.9 % normal saline by nebulizer, within ten minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Aiatollah Rohani Hospital

Full name of responsible person

Heydari Fatemeh

Street address

Ganjafrooz street

City

Babol

2

Recruitment center

Name of recruitment center

Amirkola children's hospital

Full name of responsible person

Heydari Fatemeh

Street address

Amirkola

City

Babol

3

Recruitment center

Name of recruitment center

Babol Clinic

Full name of responsible person

Heydari Fatemeh

Street address

Seyyed jamaloddin Asadabady street, Baghfardose squer

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Babol University of Medical Sciences

Full name of responsible person

Moghadamnia Aliakbar

Street address

Babol University of Medical Sciences, Ganjafrooz street

City

Babol

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, Babol 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

Babol University of Medical Sciences

Full name of responsible person

Heydari Fatemeh

Position

fellow of neonatology

Other areas of specialty/work**Street address**

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Web page address**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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Position

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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