

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the effects of nebulized ventolin in transient tachypnea of newborn

Protocol summary

Summary

Introduction: To date there is no effective drug therapy for Transient tachypnea of newborns (TTN) and respiratory support such as positive pressure and mechanical ventilation is used for these babies. Since salbutamol like β_2 -adrenergic in this regard, were used only in one study (Myo-jing) and in some cases, show positive effect and no side effects in treatment of TTN, So this clinical trial was designed. Method: In a double-blind randomized clinical trial we evaluate the effect of nebulized salbutamol in neonates with TTN. "Term/near term neonates with TTN" without "Sepsis", "pneumonia", "congenital heart disease", "Pulmonary hypertension" included and "preterm neonates with Respiratory distress syndrome", "pneumonia", "sepsis", "surfactant requirement" excluded from study and divided into two groups to get: one dose of nebulized saline 0.9% (placebo) or nebulized salbutamol. To evaluate the efficacy of any of the treatments used, we determine amount and duration of tachypnea, duration of oxygen therapy, continuous positive airway pressure or the necessity to use the ventilator in each group

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016010225811N1**

Registration date: **2016-03-18, 1394/12/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-18, 1394/12/28

Registrant information

Name

Mirhadi Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3327 2094

Email address

drmussavihadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effects of nebulized ventolin in transient tachypnea of newborn

Public title

Investigation of the effects of nebulized ventolin and saline .%9 in transient respiratory distress of newborn

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Term/near term neonates with transient tachypnea of newborn; without Sepsis; pneumonia; congenital heart disease; Pulmonary hypertension. Exclusion criteria: Preterm neonates with Respiratory distress syndrome; pneumonia; sepsis;

surfactant requirement.

Age

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

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **90**

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 Tabriz University of Medical Sciences

Street address

Av.Azadi, Av.Golgasht

City

Tabriz

Postal code

65423987456

Approval date

2015-11-21, 1394/08/30

Ethics committee reference number

TBZMED.REC.1394.701

Health conditions studied

1

Description of health condition studied

Transient tachypnoea of newborn

ICD-10 code

p22.1

ICD-10 code description

Transient tachypnoea of newborn

Primary outcomes

1

Description

Admission durations

Timepoint

during study and drug injection every 6 hour

Method of measurement

days

2

Description

CPAC application hours

Timepoint

primary 24 hours

Method of measurement

hour

3

Description

Mechanical ventilation application hours

Timepoint

primary 24 hours

Method of measurement

hour

Secondary outcomes

1

Description

Arrhymia

Timepoint

during study

Method of measurement

cardiac monitor

Intervention groups

1

Description

Intervention group: Salbutamol Glasco Compani product .1 mg/kg with 2 milliliter saline nebulization /6 hour for 24 hours

Category

Treatment - Drugs

2

Description

Control group: 2 milliliter saline nebulizationGhazi pharmaceutical company/6 hour for 24 hours

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Neonatal intensive care unite,Talegani Hospital
Full name of responsible person
Dr Mirhadi Mousavi
Street address
Av.Azadi , Av.Golgast
City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Tabriz University of Medical Sciences
Full name of responsible person
Dr.Rashidi
Street address
Av.Azadi , Av.Golgast
City
Tabriz

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,Tabriz 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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Person responsible for updating data

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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

