

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of the Effect of Intratracheal Furosemide, Salbutamol, or a Mixture of Both with Surfactant on Clinical Course of Premature Infants with Respiratory Distress Syndrome

Protocol summary

Summary

The purpose of this study is to investigate the effect of intratracheal administration of Furosemide, Salbutamol, or a mixture of both with Surfactant on the clinical course of premature infants with respiratory distress syndrome. Inclusion criteria: gestational age less than 34 weeks; respiratory distress syndrome and exclusion criteria: body weight less than 1000 g; congenital anomalies; birth trauma and perinatal asphyxia. Newborns with body weight less than 1500g with respiratory distress syndrome initially would be treated with NCPAP and 50% oxygen concentration. Based on the arterial blood gas analysis the newborns would be intubated, surfactant given and NCPAP continued or mechanical ventilation considered. Newborns with body weight greater than 1500g with respiratory distress syndrome initially would be treated with 40% oxygen concentration. If respiratory distress increases, NCPAP would be started and oxygen concentration increased up to 50%. Unresponsive patients would be intubated, surfactant given and NCPAP continued or mechanical ventilation considered. This is a double blind pilot study and 48 premature newborns with respiratory distress syndrome who need to surfactant would be enrolled in the study. Based on the table of random numbers beside of surfactant one of the following compounds would be administered intratracheally: A (Furosemide), B (Normal Saline), C (Salbutamol), D (Furosemide and Salbutamol). Duration of NCPAP treatment, need to mechanical ventilation and its duration, duration of need to oxygen and days of admission would be assessed between four groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072714215N1**

Registration date: **2014-08-13, 1393/05/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-13, 1393/05/22

Registrant information

Name

Masoud Dehdashtian

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-07-21, 1393/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Intratracheal Furosemide,

Salbutamol, or a Mixture of Both with Surfactant on Clinical Course of Premature Infants with Respiratory Distress Syndrome

Public title
The Effect of Intratracheal Furosemide, Salbutamol, or a Mixture of Both with Surfactant on Clinical Course of Neonatal Respiratory Distress Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: newborns with gestational less than 34 weeks; respiratory distress syndrome and Exclusion criteria: birth weight less than 1000gr; birth trauma; congenital anomalies; birth asphyxia; transported patients

Age
From **1 day** old to **1 month** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **48**

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
Ahvaz Jundishapur University of Medical Sciences

Street address
Golestan

City
Ahvaz

Postal code

Approval date
2014-03-15, 1392/12/24

Ethics committee reference number
ajums.REC.1392.340

Health conditions studied

1

Description of health condition studied

Respiratory Distress Syndrome

ICD-10 code

P00-P96

ICD-10 code description

certain conditions originating in the perinatal period

Primary outcomes

1

Description

Clinical course

Timepoint

Discharge from hospital

Method of measurement

Hours and days that patients needing to respiratory therapy

Secondary outcomes

1

Description

Death

Timepoint

Cardiorespiratory arrest

Method of measurement

Absent of heart beat and respiratory movement

Intervention groups

1

Description

Furosemide 1mg.kg.body weight accompanied Surfactant would be infused in trachea. if needing to repeated dose of Surfactant, Furosemide also would be repeated.

Category

Treatment - Drugs

2

Description

Salbutamol 0.2mg.kg.body weight accompanied Surfactant would be infused in trachea. if needing to repeated dose of surfactant, Salbutamol also would be repeated

Category

Treatment - Drugs

3

Description

Furosemide 1mg.kg.body weight and Salbutamol 0.2 mg.kg.body weight accompanied Surfactant would be infused in trachea. if needing to repeated dose of surfactant, Furosemide and Salbutamol also would be repeated

Category

Treatment - Drugs

4**Description**

Normal Saline 0.5ml.kg.body weight as placebo accompanied Surfactant would be infused in trachea. if needing to repeated dose of Surfactant, Normal Saline also would be repeated

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Dehdashtian Masoud, Neonatologist, Associated Professor

Street address

Azadegan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Saki Nader

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Golestan

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz Jundishapur 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**

Medical Faculty

Full name of responsible person

Dehdashtian Masoud

Position

Associate Professor, Head of Neonatal Ward

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Medical Faculty

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Position

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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