Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effect of surfactant administration during NCPAP with NCPAP alone on mortality ,morbidity and complications of RDS in premature neonates

Protocol summary

Summary

The aim of this study is to compare the effect of administration of surfactant during nasal continuous positive airway pressure (nCPAP) with only early CPAP administration for premature infants with RDS. This is a controlled randomized clinical trial on 60 premature neonates who are transported from Imam Khomeiny maternity Hospital to the NICU of Bu-Ali Hospital. Neonates with gestational age less than 35 weeks, age less or equal to 12hours after birth and the presence of symptoms of respiratory distress are placed on nCPAP and then randomly assigned to intubation and intratracheal administration of surfactant or treatment with nCPAP alone. The exclusion criteria are intubation before reaching Bu-Ali Hospital and signs and symptoms of chorioamnionitis in mother. The primary outcome is the need for mechanical ventilation on the basis of our defined criteria and the secondary outcomes are the neonatal mortality, duration of hospital stay, the incidence of intracranial hemorrhage, pulmonary hemorrhage, chronic lung disease, duration of requirement for mechanical ventilation and oxygen therapy, need for resque surfactant treatment and the number of administered doses of surfactant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205213512N2**
Registration date: **2012-06-18, 1391/03/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-06-18, 1391/03/29

Registrant information

Name

Maryam Nakhshab

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-04-20, 1391/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of surfactant administration during NCPAP with NCPAP alone on mortality ,morbidity and complications of RDS in premature neonates

Public title

The effect of the use of surfactant administration during NCPAP treatment on complications of RDS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: gestational age less than 35 weeks;

age less or equal to 12 hours after birth; the presence of symptoms of respiratory distress syndrom (RDS); symptoms begun in the first 6 hours after birth; radiologic signs for RDS in chest radiography. The exclusion criteria: 5 minutes Apgar score less than 6; intubation before reaching Bu-Ali Hospital, presence of major anomalies, PROM> 12 hours, admission to Bu-Ali Hospital after 12 hours of age, signs and symptoms of chorioamnionitis in mother, beginning of respiratory distress after 6 hours of birth, need for mechanical ventilation (on the basis of our defined criteria) at the time the patient reaches to Bu-Ali Hospital.

Age
To **1 year** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mazandaran University of Medical Sciences

Street address
Vice-Chancellor for Research, Moalem sq., Sari, Mazandaran, Iran

City
Sari

Postal code

Approval date
2011-03-02, 1389/12/11

Ethics committee reference number
89-166

Health conditions studied

1

Description of health condition studied
Respiratory Distress Syndrome in the newborn

ICD-10 code
P22.0

ICD-10 code description
Respiratory Distress syndrome

Primary outcomes

1

Description
need for mechanical ventilation

Timepoint
daily within the first week of life

Method of measurement
physical exam for significant respiratory distress and/or the presence of persistent or recurrent apnea and check of ABG for hypoxia or respiratory acidosis .

Secondary outcomes

1

Description
neonatal mortality

Timepoint
during hospitalization

Method of measurement
hospital documents

2

Description
duration of hospital stay

Timepoint
during of hospitalization

Method of measurement
hospital documents

3

Description
the incidence of pneumothorax

Timepoint
till 72 hours after birth

Method of measurement
CXR

4

Description
pulmonary hemorrhage

Timepoint
till 72 hours after birth

Method of measurement
cilinical diagnosis and CXR

5

Description
number of rescue doses of surfactant

Timepoint

till 48 hours after birth

Method of measurement

hospital documents

6

Description

the incidence of chronic lung disease (CLD)

Timepoint

till 36 weeks’ postnatal age

Method of measurement

oxygen requirement at 36 weeks’ postnatal age

7

Description

intraventricular hemorrhage (IVH)

Timepoint

7-14 days after birth

Method of measurement

brain sonography

8

Description

periventricular leukomalacia (PVL)

Timepoint

between 36 and 40 weeks; postnatal age

Method of measurement

brain sonography

9

Description

the incidence of retinopathy of prematurity

Timepoint

4 weeks' of age and then every week till vascularization is completed

Method of measurement

eye exam

10

Description

duration of mechanical ventilation

Timepoint

during hospital stay

Method of measurement

hospital documents

11

Description

duration of need for oxygen

Timepoint

during hospital stay

Method of measurement

hospital documents

Intervention groups

1

Description

In control group nasal CPAP of 6 cm H2O is administered for the patients and the infant remains on NCPAP.Any patient who needs mechanical ventilation (according to criteria below) is intubated and placed under intermittent mandatory ventilation (IMV) and is considered as nCPAP failure in control group. If needed Fio2 is more than 30% the resque dose of surfactant (Survanta) is administered. Additional surfactant doses are given every 6 hours as long as Fio2 remains more than 30% but not after 48 hours of age

Category

Treatment - Devices

2

Description

In the treatment group the patient is placed on nCPAP and then temporarily intubated. A natural surfactant (Survanta , Abbot Laboratories, Abbot Park, IL) 100 mg/Kg is administered intratrachealy and the neonate is ventilated manually with Neopuff infant resuscitator (Fisher & Paykel Healthcare, Inc, Auckland, New Zealand) with peak inspiratory pressure of 20 cm H2O and positive-end expiratory pressure of 5 cm H2O only for some minutes and if the patient is stable extubation to NCPAP of 5 cm H2O is accomplished. Every patient on CPAP would receive Aminophylline with a loading dose of 5 mg/Kg and then 1 mg/Kg every 8 hour intravenously. Any patient who needs mechanical ventilation is intubated and placed under intermittent mandatory ventilation (IMV) and is considered as INSURE failure in treatment group . If needed Fio2 is more than 30% the resque dose of surfactant (Survanta) is administered. Additional surfactant doses are given every 6 hours as long as Fio2 remains more than 30% but not after 48 hours of age.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali Hospital

Full name of responsible person

Maryam Nakhshab

Street address

Bu-Ali Hospital, Sari, Mazandaran, Iran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Siences

Full name of responsible person

Ahmad Ali Enayati

Street address

Mazandaran University of Medical Siences, Moalem Sq., Sari, Mazandaran, Iran

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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

Mazandaran University of Medical Siences

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

Mazandaran University of Medical Siences

Full name of responsible person

Maryam Nakhshab

Position

assisstant professor/MD

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Email

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