

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the Effect of Supine and Prone Position on duration of respiratory support in Premature newborns with RDS receiving NCPAP

Protocol summary

Study aim

Comparison of duration of NCPAP: CPAP level: Duration of hospitalization: Need for mechanical ventilation: Incidence of BPD: Incidence of air leak syndrome: Duration for full enteral feeding: Number of surfactant administration

Design

Two arm parallel group randomised trial with outcome assessment on 136 preterm newborns

Settings and conduct

The study was conducted on preterm newborns affiliated from RDS in hospitals dependent to Isfahan University of Medical Sciences

Participants/Inclusion and exclusion criteria

This study was a randomized clinical trial on 136 preterm newborns with gestational age between 30 to 34 week affiliated with RDS hospitalized in centers dependent to Isfahan University of Medical Sciences and need for respiratory support via NCPAP.

Intervention groups

Newborns in control group receive NCPAP in supine position and surfactant administrate using INSURE technique according to the definitive criteria. newborns in case group receive NCPAP in prone position and only for feeding and routine care position change to supine and if time of supine position last more than 3 hours per day exit from study. In two groups the manner of surfactant administration and weaning are same.

Main outcome variables

Duration of NCPAP: CPAP level: Duration of hospitalization: Need for mechanical ventilation: Incidence of BPD: Incidence of air leak syndrome: Duration for full enteral feeding: Number of surfactant administration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150423021910N6**

Registration date: **2020-10-18, 1399/07/27**

Registration timing: **retrospective**

Last update: **2020-10-18, 1399/07/27**

Update count: **0**

Registration date

2020-10-18, 1399/07/27

Registrant information

Name

Behzad Barekatin

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2020-09-21, 1399/06/31

Trial completion date

2020-09-21, 1399/06/31

Scientific title

Comparison of the Effect of Supine and Prone Position on duration of respiratory support in Premature newborns with RDS receiving NCPAP

Public title

Effect of Position on duration of respiratory support in Premature newborns with RDS receiving NCPAP

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age between 30 to 34 W Affiliated from RDS
Mother received one course of steroid therapy before delivery

Exclusion criteria:

Lack of Congenital Heart Disease Lack of Defects
interfere with specific position Lack of Perinatal Asphyxia
Lack of maternal chorioamnionitis

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **136**

Actual sample size reached: **134**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is simple and individuals.table of random numbers use to randomization. at first one row and one column selected randomly and conflux point of row and column was consider as initial point of sampling. then top down even numbers and odd numbers accrue to case and control groups respectively.for allocation concealment 136 envelopes prepare and random numbers register .after closure of envelopes, we put those into the box.according to the order of patients one of the envelopes open and patients allocate to case or control groups.

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**

Ethics committee of Isfahan University of Medical Sciences

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Hezarjerib boulevard, Isfahan University of Medical

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8174673461

Approval date

2017-12-04, 1396/09/13

Ethics committee reference number

IR.MUI.REC.1396.1.142

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

Respiratory Distress Syndrom

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

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

Duration of CPAP

Timepoint

Hour

Method of measurement

Questionnaire

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

Mean of CPAP

Timepoint

During study

Method of measurement

CPAP desktop

2**Description**

Duration of hospitalization

Timepoint

Daily

Method of measurement

Questionnaire

3**Description**

Need for mechanical ventilation

Timepoint

During study

Method of measurement

Clinical examination

4

Description

Bronchopulmonary dysplasia

Timepoint

During study

Method of measurement

Clinical examination

5

Description

Pneumothorax

Timepoint

During study

Method of measurement

Chest X ray

6

Description

Time to full enteral feeding

Timepoint

During study

Method of measurement

Clinical examination

7

Description

The number of surfactant administration

Timepoint

During study

Method of measurement

Clinical examination

Intervention groups

1

Description

Intervention group: The newborns in case group put in prone position and only for feeding and nurse care position change to supine for maximum 15 minute. respiratory support was established with NCPAP (Bubble CPAP Infant Delivery System, Fisher & Paykel, Auckland, New Zealand); at first CDP equal to 6-8 cmH₂O and FiO₂=30% was administrated. In case, the newborn needed inspiratory oxygen fraction of higher than 40% to maintain oxygen saturation in the right hand at 90-95% for more than 1 hour, the newborn would receive 200 mg/kg of Crusorf per INSURE method. In case, the newborn's need for the inspiratory oxygen fraction of higher than 40% was consistent to maintain the oxygen saturation level in an acceptable range, after 12 h from the last administration of surfactant, Crusorf (100 mg/kg) would be administered again, and as necessary, the full course of treatment (maximum 3 dose) would be observed. after stabilization under CPAP for more than 12 hour, CDP decrease every 4 hour and in the setting as CDP=4 cmH₂O and FiO₂<25% newborn wean from NCPAP.

Category

Treatment - Devices

2

Description

Control group: The newborns in control group put in supine position. respiratory support was established with NCPAP (Bubble CPAP Infant Delivery System, Fisher & Paykel, Auckland, New Zealand); at first CDP equal to 6-8 cmH₂O and FiO₂=30% was administrated. In case, the newborn needed inspiratory oxygen fraction of higher than 40% to maintain oxygen saturation in the right hand at 90-95% for more than 1 hour, the newborn would receive 200 mg/kg of Crusorf per INSURE method. In case, the newborn's need for the inspiratory oxygen fraction of higher than 40% was consistent to maintain the oxygen saturation level in an acceptable range, after 12 h from the last administration of surfactant, Crusorf (100 mg/kg) would be administered again, and as necessary, the full course of treatment (maximum 3 dose) would be observed. after stabilization under CPAP for more than 12 hour, CDP decrease every 4 hour and in the setting as CDP=4 cmH₂O and FiO₂<25% newborn wean from NCPAP.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

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2

Recruitment center

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Sponsors / Funding sources

1

Sponsor

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more informations

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available