Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing sudden Complete and gradual weaning on successful weaning from nasal CPAP in preterm infants

Protocol summary

Study aim
Comparing sudden complete versus gradual weaning from nasal continuous positive airway pressure (NCPAP) in preterm infants

Design
Two arm parallel group randomized singleblind clinical trial

Settings and conduct
Location of study: Isfahan NICU wards. Blinding method: Single blind, in which parents were kept unaware of the study (intervention) group.

Participants/Inclusion and exclusion criteria
Inclusion criteria :Preterm infants younger than 32 weeks of gestation; 5-minute Apgar score over 4. Exclusion criteria: congenital heart anomalies (except for small atrial septal defect, patent foramen ovale, and patent ductus arteriosus (PDA)); definitely or possibly diagnosed neuromuscular diseases; the need for surgery

Intervention groups
Intervention group: infant is separated from NCPAP and is allowed to breathe in the room air with FiO2 of 21% or with extra oxygen with FiO2 of 40% for 4 hours. Control group: sudden complete weaning, the infant is separated completely from the set and is allowed to breathe in room air (FiO2 = 21%) or with extra oxygen with FiO2 of maximally 40%.

Main outcome variables
successful NCPAP weaning in the first attempt.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180915041040N1**
Registration date: **2018-11-30, 1397/09/09**
Registration timing: **retrospective**
Last update: **2018-11-30, 1397/09/09**
Update count: **0**

Registration date
2018-11-30, 1397/09/09

Registrant information

Name
Roya Choopani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 38 3222 0016

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2014-11-03, 1393/08/12

Expected recruitment end date
2015-12-11, 1394/09/20

Actual recruitment start date
2014-11-03, 1393/08/12

Actual recruitment end date
2015-12-11, 1394/09/20

Trial completion date
2016-08-31, 1395/06/10

Scientific title
Comparing sudden Complete and gradual weaning on successful weaning from nasal CPAP in preterm infants

Public title
weaning from nasal continuous positive airway pressure in preterm infants

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age equal to or less than 32 weeks and birth weight equal to or less than 1800 gr Starting NCPAP from first hours of birth to treat respiratory distress syndrome Treatment with NCPAP after weaning from positive pressure ventilation via endotracheal route The newborn should be under treatment with NCPAP for at least 24 hours 5th minute APGAR score above 4

Exclusion criteria:

Documented congenital heart anomalies (except for small atrial septal defect, patent foramen ovale, and patent ductus arteriosus (PDA)) definite or possible neuromuscular disease definite or possible syndrome need for surgery transfer to other hospital patients weighing less than 750 g at the time of randomization intraventricular hemorrhage (grade above 2) lung hypoplasia other life-threatening congenital anomalies thoracic or airway anomalies need for mechanical ventilation before NCPAP removal

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization Using random numbers table

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blind. Parents of neonates were kept unaware of the groups their neonate was allocate to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjarib st. Isfahan

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2014-08-24, 1393/06/02

Ethics committee reference number

393348

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome of newborn

ICD-10 code

P22

ICD-10 code description

Respiratory distress of newborn

Primary outcomes

1

Description

successful NCPAP weaning in the first attempt

Timepoint

After first attempt to NCPAP weaning

Method of measurement

Number of attempts

Secondary outcomes

1

Description

The frequency of weaning

Timepoint

After each time of weaning from the device

Method of measurement

Document

Intervention groups

1

Description

Intervention group: infant is separated from NCPAP and is allowed to breathe in the room air with FiO2 of 21% or with extra oxygen with FiO2 of 40% for 4 hours. Then, NCPAP with 5 cm H2O PEEP and FiO2 of 21% is applied for 6 hours. Under a stable clinical condition over the 6 hours, weaning is performed and the duration of separation is increased every 4 hours up to 12 hours. The duration of NCPAP between weaning intervals will be constant, i.e., 6 hours. In the next step, when the infant is weaned for 12 hours and no criteria of treatment failure is occurred, NCPAP is continued for additional 6 hours and then, the infant is completely weaned.

Category
Treatment - Devices

2

Description
Control group: sudden complete weaning, the infant is separated completely from the set and is allowed to breathe in room air (FiO2 = 21%) or with extra oxygen with FiO2 of maximally 40%
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
NICUs in Isfahan
Full name of responsible person
Roya Choopani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Shaghayegh Hagh joo
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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
Esfahan University of Medical Sciences
Full name of responsible person
Roya Choopani
Position
Assistant professor
Latest degree
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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
"There is no more information."
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