

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Continuous Positive Airway Pressure or High Flow Nasal Cannula for Respiratory Distress Syndrome: a Randomized Control Trail among Premature Infants

Protocol summary

Study aim

comparison of the efficacy of CPAP and HFNC methods in the treatment of Iranian premature infants with RDS

Design

Clinical trial with control group, with parallel groups, one blind, randomized

Settings and conduct

This randomized control trail study was conducted among 60 infants suffering from RDS in Imam Khomeini Hospital Complex, Valiasr Hospital, in Tehran city, during 2018. Infants in the neonatal intensive care unit (NICU) of Valiasr Hospital participated in the study.

Participants/Inclusion and exclusion criteria

Only the infant's with mild to moderate RDS, birth weight less than 2000 grams, gestational age less than 34 weeks, respiratory severity between 4 to 7 score, and requires oxygen 60% or less were eligible to participate in this study. As well as, infants who had heart, digestive and respiratory anomalies, intraventricular hemorrhage (IVH) at birth, persistent air leak, sepsis positive at hospitalization in NICU, and Apgar score of less than 5 at 5 minutes were considered to exclusion criteria in this study.

Intervention groups

CPAP treatment was 4 to 6 cm water and FIO₂ equivalent to 30% to improve respiratory distress and to reduce the need for oxygen for newborns. The positive pressure created by the device for the infants was measured by a manometer at the beginning of the respiratory tube expiratory arm. It should be noted that treatment was carried out on infants in supine position. Infants in another group were treated with HFNC methods, and this method continued to improve respiratory distress and eliminate the need for oxygen. Oxygen was heated with a blender unit with a temperature of 32 to 35 °C, and the infant's mouth was kept open during the use of the upper flow. Regulation flow was calculated based on the

following formula: flow rate (liters per minute) = weight (kilograms) & 0.86 + 0.92

Main outcome variables

treatment of infants with RDS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190623043988N1**

Registration date: **2019-07-05, 1398/04/14**

Registration timing: **retrospective**

Last update: **2019-07-05, 1398/04/14**

Update count: **0**

Registration date

2019-07-05, 1398/04/14

Registrant information

Name

Seyyed Nasrollah Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8804 7711

Email address

hosseini.seyyednasrollah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-01-03, 1395/10/14

Expected recruitment end date

2018-06-19, 1397/03/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Continuous Positive Airway Pressure or High Flow Nasal Cannula for Respiratory Distress Syndrome: a Randomized Control Trail among Premature Infants

Public title
Continuous Positive Airway Pressure or High Flow Nasal Cannula for Respiratory Distress Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 birth weight less than 2000 grams, gestational age less than 34 weeks respiratory severity between 4 to 7 score requires oxygen 60% or less
Exclusion criteria:

Age
From **1 day** old to **29 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual Randomization Permuted (block randomization) one infant in CPAP group and one infant in HFNC group

Blinding (investigator's opinion)
Single blinded

Blinding description
Single-way: patients In our study, only patients were blind Researchers and data analyst knew the treatment groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

This study was approved by the Institutional Ethics

Committee of the Tehran University of Medical Sc

Street address
Ghods Town, Iran's Broadcasting Street, between Falamak and Zarafshan, Headquarters of the Ministry of Health and Medical Education

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2017-01-19, 1395/10/30

Ethics committee reference number

IR.TUMS.IKHC.REC.1395.1477

Health conditions studied

1

Description of health condition studied

Respiratory Distress Syndrome

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

evaluate Continuous Positive Airway Pressure (CPAP) and High Flow Nasal Cannula (HFNC) intervention effectiveness among premature infants with RDS

Timepoint

Until the end of the breathtaking Rage

Method of measurement

evaluate Continuous Positive Airway Pressure (CPAP) and High Flow Nasal Cannula (HFNC) intervention effectiveness among premature infants with RDS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Overall, 60 preterm infants with RDS at Valiasr Hospital, Tehran, during 2018 in this randomized control trail participated as CPAP and HFNC groups' treatment. CPAP group received the nose with a peep of 4-6 centimeters from birth and continued to improve respiratory distress and the need for oxygen (O2). HFNC group received hot and humid flowing 2 to 5 liters/min in nose cannula, until respiratory distress and O2 needing to be resolved

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital, Tehran

Full name of responsible person

Seyyed Nasrollah Hosseini

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hosseiniseyyednasrollah@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seyyed Nasrollah Hosseini

Street address

Tehran, Ghods Town, Iran's Simay Ave., Between
Falamak and Zarafshan, Headquarters of the Ministry
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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Seyyed Nasrollah Hosseini

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Tehran, Ghods Town, Iran's Simay Ave., Between
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seyyed Nasrollah Hosseini

Position

Assistant Professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document**When the data will become available and for how long**

Start the access period 6 months after publish the results

To whom data/document is available

Health professionals

Under which criteria data/document could be used

Please contact the corresponding author for data requests.

From where data/document is obtainable

Please contact the corresponding author for data requests.

What processes are involved for a request to access data/document

Please contact the corresponding author for data requests.

Comments