Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy of nasal high frequency oscillatory ventilation versus nasal continuous positive airway pressure and double positive airway pressure in neonates less than 34 weeks with respiratory distress syndrome: a randomized controlled trial.

Protocol summary

Study aim

Comparison between 3 non invasive method include NHFOV, CPAP and DUOPAP in treatment of neonates less than 34 weeks, birth weight 1000- 2000 gr with respiratory disress syndrome(RDS) admitted in ahwaz emam khomeini hospital.

Design

Randomised, blined, parallel group trial with 192 patients. Randomisation with sealedenvelope website.

Settings and conduct

First select six senary blocks and then numbers of one to six are assigned. The statistician randomly selects a number between one to six , And based on the obtained sequence patients are randomly placed in one of groups a, b, c. And the above sequence continues until the patient reaches the number 64 in each group. Patient (neonate) and care giver in NICU are blind and have no idea about study. Then each neonate get one of 3 treatment, randomaisly.

Participants/Inclusion and exclusion criteria

Premature neonates less than 34 gestational age، birth weight 1000 - 2000 gr with RDS admitted in ahwaz emam khomeini hospital (in 6 first hours of life) enter in study. Great anomaly, airway anomaly, cardiovascular instability, sever asphyxia and parents dissatisfaction are exclusion factors.

Intervention groups

3 non invasive respiratory support nasal high frequency oscillatory ventilation(NHFOV) versus nasal continuous positive airway pressure(NCPAP) and double positive airway pressure (DUOPAP) in neonates

Main outcome variables

Failure in NIV and intubation duration 48 hr after start NIV

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240130060854N1**
Registration date: **2024-02-21, 1402/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-21, 1402/12/02**
Update count: **0**

Registration date

2024-02-21, 1402/12/02

Registrant information

Name

Misagh Najarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3551 5239

Email address

misagh.70.mn@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-18, 1402/11/29

Expected recruitment end date

2025-02-17, 1403/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy of nasal high frequency oscillatory ventilation versus nasal continuous positive airway pressure and double positive airway pressure in neonates less than 34 weeks with respiratory distress syndrome: a randomized controlled trial.

Public title
Efficacy of nasal high frequency oscillatory ventilation versus nasal continuous positive airway pressure and double positive airway pressure in neonates less than 34 weeks with respiratory distress syndrome: a randomized controlled trial.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Premature neonates less than 34 gestational age Birth weight 1000 - 2000 gr Admitted in ahwaz emam khomeini hospital In 6 first hours of life

Exclusion criteria:
Great anomaly Airway anomaly Cardiovascular instability Sever asphyxia Parents dissatisfaction

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **192**

Randomization (investigator's opinion)
Randomized

Randomization description
First select six senary blocks and then numbers of one to six are assigned. The statistician randomly selects a number between one to six , And based on the obtained sequence patients are randomly placed in one of groups a, b, c. And the above sequence continues until the patient reaches the number 64 in each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are neonats. Clinical observers do routine care and have no idea about members and study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahwaz jondishapour university of medical science ethic committee

Street address
No. 96, west 17 Ave., padadshahr Blvd.

City
Ahwaz

Province
Khouzestan

Postal code
6183967541

Approval date
2024-02-18, 1402/11/29

Ethics committee reference number
330102012

Health conditions studied

1

Description of health condition studied
Respiratory distress syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Failure in NIV and intubation duration 48 hr after start NIV

Timepoint
The neonate is non-invasively monitored under the supervision of a clinical caregiver at all hours of the day and if intubation is needed based on the protocol defined in the implementation of the reearch, the neonate is intubated and recorded in the neonate information collection questionnaire.

Method of measurement
With examination and chest x- ray

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: treatment with NHFOV / Second intervention group: treatment with CPAP / Third intervention group: treatment with DUOPAP

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam khomeini hospital
Full name of responsible person
Arash malekian
Street address
No. 96 , west 17 Ave., padadshahr Blvd
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Meisam moezi
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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 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
Ahvaz University of Medical Sciences
Full name of responsible person
Arash malekian
Position
Associated professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available
Title and more details about the data/document
Personal data of participants can be shared after unidentifiable
When the data will become available and for how long
The access period starts 6 month after the publication of the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Use for systematic review articles Journal reviewer's request to review the information
From where data/document is obtainable
Corresponding author
What processes are involved for a request to access data/document
Researchers request from corresponding author
Comments