

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 distress syndrome(RDS) admitted in ahwaz emam khomeini hospital.

Design

Randomised, blinded, parallel group trial with 192 patients. Randomisation with sealed envelope 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

City

Ahwaz

Province

Khouzestan

Postal code

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Phone

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Email

Misagh.70.mn@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Meisam moezi

Street address

No. 96, West 17 Ave., Padadshahr

City

Ahwaz

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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 updating data

Contact

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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