

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 imam 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 imam 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

Khuzestan

##### 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 research, 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**

6183967541

**Phone**

+98 61 3551 5239

**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

**Province**

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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

**Street address**

No. 96, West 17 Ave., Padadshahr

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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**