Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

Comparison of the effect of (NSIMV) Nasal Synchronized Intermittent Mandatory Ventilation whit (NHFOV) Nasal high frequency oscillatory ventilation in neonates requiring non-invasive mechanical ventilation in Mofid Pediatric Hospital

Protocol summary

Study aim

Comparing effect of Nasal Synchronized Intermittent Mandatory Ventilation with Nasal high frequency oscillatory ventilation in infants who need non invasive ventilation

Design

This double-blind two phaseic clinical trial study with a parallel group, 180 premature babies needing non-invasive mechanical ventilation will be divided into two groups, Nasal high frequency oscillatory ventilation and Nasal Synchronized Intermittent Mandatory Ventilation, using a simple randomization method.

Settings and conduct

One hundred eighty infants who need non-invasive mechanical ventilation admitted to Mufid Children's Hospital, Tehran, Iran will be allocated to two groups by a simple randomization method. The duration of the intervention will be adjusted based on the needs of the infant. The therapist is responsible for the study and the infant is not involved in the allocation of the intervention group. In addition, the researcher and the data analyst are not involved in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Premature infants with a gestational age of more than 26 weeks needing respiratory support Exclusion criteria: intubation before randomization, long-term resuscitation, lack of parental consent, infants with contraindication of non-invasive mechanical ventilation, infants with head and face anomalies, grade 3 and 4 intraventricular hemorrhage.

Intervention groups

Intervention group 1: non-invasive mechanical ventilation with Nasal Synchronized Intermittent Mandatory Ventilation mode intervention group 2: non-invasive mechanical ventilation with nasal HFO mode

Main outcome variables

Duration of need for mechanical ventilation in premature infants under study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056556N1**
Registration date: **2023-01-24, 1401/11/04**
Registration timing: **prospective**

Last update: **2023-01-24, 1401/11/04**
Update count: **0**

Registration date

2023-01-24, 1401/11/04

Registrant information

Name

Minoo Fallahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of (NSIMV) Nasal Synchronized Intermittent Mandatory Ventilation whit (NHFOV) Nasal high frequency oscillatory ventilation in neonates requiring non-invasive mechanical ventilation in Mofid Pediatric Hospital

Public title

Comparison of the effect of (NSIMV) Nasal Synchronized Intermittent Mandatory Ventilation whit (NHFOV) Nasal high frequency oscillatory ventilation in neonates requiring non-invasive mechanical ventilation in Mofid Pediatric Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria include: Premature babies hospitalized in the intensive care unit with a gestational age of more than 26 weeks who need respiratory support. Informed consents of the baby's parents

Exclusion criteria:

Babies who were intubated for resuscitation or for another reason before randomization. cardio-pulmonary arrest requiring prolonged resuscitation lack of consent of the baby's parents Transferring the baby out of the neonatal intensive care unit before randomization In infants with the contraindication of non-invasive mechanical ventilation, such as infants with esophageal atresia or diaphragmatic hernia within 10 to 14 days after surgery Babies with head and face anomalies that do not allow ventilation inside the baby's nose, such as cleft lip and palate Intraventricular hemorrhage in grade 3 and 4

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **180**

More than 1 sample in each individual

Number of samples in each individual: **90**

The studied population, all babies with a gestational age of more than 26 weeks and less than 37 weeks will need mechanical ventilation admitted to Mofid Children's Hospital in Tehran. Also, all babies with contraindications for non-invasive mechanical ventilation, such as babies with head and face anomalies, grade 3 and 4 intracerebral hemorrhage, cardiopulmonary arrest, lack of parental consent, will be excluded from the study. The number of 180 infants with inclusion criteria will be divided into two groups, nasal high frequency oscillatory ventilation (NHFOV) and nasal synchronized intermittent mandatory ventilation (NSIMV), based on simple randomization. The initial settings in the NHFOV group were as follows: frequency of 10 Hz (subsequent regulation range, 8-12, in steps of 1 Hz); inspiratory time of 50% (1:1)19; an oscillation amplitude (delta P) of 20-35 cm H2O Fio2: 30-40% The initial settings in the NSIMV group were as follows: PIP: 14-16 cmH2O PEEP: 5-6 cmH2O Rate: 30-40 Ti: 0.4 FiO2 : 30-40% then information related to the baby's gestational age, birth weight, baby's sex, Apgar 1st minute, Apgar 5th minute, Apgar 10th minute, Antenatal corticoids, type of delivery, gestational diabetes, duration of treatment under mechanical ventilation, use of Surfactant and oxygen level before extubation, primary outcomes (re-intubation, blood carbon dioxide pressure) and secondary outcomes (Incidence of Intraventricular hemorrhage, Patent ductus arteriosus, Retinopathy of permaturity, Bronchopulmonary dysplasia, Necrotizing enterocolitis, duration of hospitalization and death in each Two groups will be collected.

Randomization (investigator's opinion)

Randomized

Randomization description

Premature babies needing non-invasive mechanical ventilation are divided into two non-invasive mechanical ventilation groups(HFO and SIMV) using simple randomization method and random number table. So that patients who met the criteria s to enter the study will be assigned a number, and then without prior knowledge, even numbers will be placed in the intervention group and odd numbers will be placed in the control group. In this way, each member of the community will have an equal chance to be selected in order to be included in both intervention and control groups, and the researcher will not interfere in the selection of samples.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, premature babies who need non-invasive mechanical ventilation will be divided into two groups. Due to the study method and the impossibility of blinding mechanical ventilation, the doctor and nurse caring for the baby will be informed about the selected method for non-invasive mechanical ventilation, but the statistical analyzer of the research will not be informed about the allocation of patients in two groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Shahid Beheshti University of Medical Scences
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
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Province
Tehran
Postal code
1983963113
Approval date
2022-07-19, 1401/04/28
Ethics committee reference number
IR.SBMU.MSP.REC.1401.186

Health conditions studied

1

Description of health condition studied
Respiratory Distress Syndrome/ Prematurity
ICD-10 code
P22
ICD-10 code description
Respiratory distress of newborn

Primary outcomes

1

Description
Duration of need for mechanical ventilation in premature infants under study
Timepoint
In the total hospitalization time of the premature baby under study in the neonatal intensive care unit
Method of measurement
The number of days without the need for mechanical ventilation in the baby

Secondary outcomes

1

Description
Patent ductus arteriosus
Timepoint
During the hospitalization of the baby
Method of measurement
Echocardiography by pediatric cardiologist

2

Description
Retinopathy of permaturity
Timepoint
During the hospitalization of the baby
Method of measurement
By Ophthalmologist retina subspecialties

3

Description
Intraventricular hemorrhage
Timepoint
During the hospitalization of the baby
Method of measurement
Brain sonography by pediatric radiologist

4

Description
Necrotizing enterocollitis
Timepoint
During the hospitalization of the baby
Method of measurement
Clinical sings according to BELL score and abdominal sonography by pediatric radiologist

5

Description
Bronchopulmonary dysplasia
Timepoint
During the hospitalization of the baby
Method of measurement
Clinical signs and radiologic findings

Intervention groups

1

Description
Intervention group: Premature babies with a gestational age of more than 26 weeks need non-invasive mechanical ventilation
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Children"s Hospital
Full name of responsible person
Minoo Fallahi
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7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Afshin Zarghi

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
minoo fallahi

Position
associated professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available