Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of routine chest physiotherapy and expiratory techniques on oxygenation and expiratory volume of preterm infants with respiratory distress syndrome

Protocol summary

Study aim
The effect of routine chest physiotherapy and expiratory techniques on oxygenation and expiratory volume of preterm infants with respiratory distress syndrome

Design
Clinical trial, unblinded, Simple randomized.

Settings and conduct
the neonatals with entry criteria in the NICU of Afzalipur hospital, Kerman, where the diagnosis of the syndrome was based on history, examination and clinical symptoms including respiratory rate, breathing pattern, paraclinical including arterial blood gases (ABG), radiology and also the use of ventilator by doctor. First, the work steps will be fully explained to the families of premature newborns, and the consent form and questionnaire will be completed by their families. Then the neonatals are randomly assigned to two groups.

Participants/Inclusion and exclusion criteria
Entry criteria: Premature infants weighing less than 3 kg; Age between 32-37 weeks of pregnancy; RDS diagnosed by a specialist doctor; On the first 28 days of birth; Be intubated; There is no known cardiac or neurological problem or candidate for surgery; The neonatal girl or boy; No entry criteria: Unwillingness to enter the study

Intervention groups
Group of routine chest physiotherapy including: chest vibration, percussion, pastural drainage Group of exhalation techniques including: prolonged slow expiratory, expiratory flow increased, lung squeezing technique and vojta with routine chest physiotherapy

Main outcome variables
Expiratory volume(Vte), hemoglobin saturation O2sat., The duration of intubation, Inspiration Rate, Fio2, Mean airway pressure(MAP) during the entire inspiratory and expiratory time, PEEP, PIP.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180714040466N5**
Registration date: **2023-10-06, 1402/07/14**
Registration timing: **prospective**

Last update: **2023-10-06, 1402/07/14**
Update count: **0**

Registration date
2023-10-06, 1402/07/14

Registrant information

Name
Fateme Ghiasi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

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
The effect of routine chest physiotherapy and expiratory techniques on oxygenation and expiratory volume of preterm infants with respiratory distress syndrome

Public title
The effect of routine chest physiotherapy and expiratory techniques on oxygenation and expiratory volume of preterm infants
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Premature infants aged between 32-37 weeks of pregnancy RDS diagnosed by a specialist doctor Be in the first 28 days of birth Be intubated She or he does not have a known heart or neurological problem or a candidate for surgery The neonatal girl or boy
Exclusion criteria:
Unwillingness to enter the study
Age
From **1 day** old to **28 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization as follows: Based on the number of patients in each group, the particular sort of treatment (routine chest physiotherapy group or expiratory techniques with routine chest physiotherapy group) is written on a piece of paper. Each paper is placed in a sealed envelope. One envelope will be chosen randomly by the therapist at the first session of the patient treatment and the patient's treatment technique is selected based on that .If any of the patients is omitted from the study, one envelope related to the excluded patient treatment group will be replaced and they will mixed again.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences
Street address
Dr. Hesabi Street
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2023-08-20, 1402/05/29
Ethics committee reference number
IR.ZAUMS.REC.1402.233

Health conditions studied

1

Description of health condition studied
Respiratory distress syndrome of newborn
ICD-10 code
P22.0
ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Expiratory volume (Vte)
Timepoint
Before physiotherapy and 15 minutes after physiotherapy
Method of measurement
Expiratory volume recorded on the ventilator

2

Description
Oxygen saturation of hemoglobin (O2sat)
Timepoint
Before physiotherapy and 15 minutes after physiotherapy
Method of measurement
The percentage recorded on the monitor by the pulse oximeter

3

Description
Number of breaths per minute
Timepoint
Before physiotherapy and 15 minutes after physiotherapy
Method of measurement
The rate of breaths recorded on the ventilator

4

Description
The fraction of inspired oxygen (Fio2)
Timepoint
Before physiotherapy and 15 minutes after physiotherapy
Method of measurement
The percentage recorded by the ventilator

5

Description
Mean airway pressure (MAP)
Timepoint
Before physiotherapy and 15 minutes after physiotherapy
Method of measurement
The number recorded on the ventilator

6

Description
Positive end expiratory pressure (PEEP)
Timepoint
Before physiotherapy and 15 minutes after physiotherapy
Method of measurement
The number recorded on the ventilator

7

Description
Peak inspiratory pressure
Timepoint
The number recorded on the ventilator
Method of measurement
The number recorded on the ventilator

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A group are the neonatals diagnosed with respiratory distress syndrome who will be admitted and intubated in the neonatal intensive care unit of Afzalipour hospital in Kerman will be examined if they meet the conditions for entering the study. Diagnosis of the syndrome is based on history, examination and clinical symptoms including respiratory rate, breathing pattern, paraclinical including arterial blood gases, (ABG) radiology and also the use of ventilator by the doctor. First, the work steps are fully will be explained to the families of premature newborns, and the consent form and questionnaire will be completed by their families. Then the newborns are randomly placed in this group and routine physiotherapy techniques including chest vibration, percussion, pastural drainage and exhalation techniques including prolonged slow expiratory, expiratory flow increased, lung squeezing technique and vojta twice a day with a time interval of eight hours, five days while the patient's stomach is empty one hour before to prevent aspiration, it will be done in two shifts in the morning and in the evening according to the doctor's order. The evaluated variables will be recorded before doing the physiotherapy and then fifteen minutes after doing the respiratory physiotherapy, which is displayed by the ventilator device.
Category
Rehabilitation

2

Description
Routine group: B group are the neonatals diagnosed with respiratory distress syndrome who will be admitted and intubated in the neonatal intensive care unit of Afzalipour hospital in Kerman will be examined if they meet the conditions for entering the study. Diagnosis of the syndrome is based on history, examination and clinical symptoms including respiratory rate, breathing pattern, paraclinical including arterial blood gases (ABG), radiology and also the use of ventilator by the doctor. First, the work steps fully will be explained to the families of premature newborns, and the consent form and questionnaire will be completed by their families. Then the newborns are randomly placed in this group with routine physiotherapy techniques including: chest vibration, percussion and postural drainage on them twice a day with a time interval of eight hours, five days while the patient's stomach is empty one hour before to prevent aspiration, it will be done in two shifts in the morning and in the evening according to the doctor's order. The evaluated variables will be recorded before doing the physiotherapy and then fifteen minutes after doing the respiratory physiotherapy, which is displayed by the ventilator device.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Neda Madadizadeh
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Fateme Ghiasi
Position
Assistance professor
Latest degree
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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)
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