

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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, postural 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

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 6708

Email address

f_ghiasi_p@zaums.ac.ir

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, pastoral 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 Madadzadeh

Street address

Imam Khomeini Street

City

Kerman

Province

Kerman

Postal code

7616913355

Phone

+98 34 3132 8000

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Noormohammad Bakhshani

Street address

Dr. Hesabi street

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3337 2151

Email

public@zaums.ac.ir

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

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Khatam al anbia Hosp, Jame jam Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9815733169

Phone

+98 54 3322 0501

Email

f_ghiasi_p@zaums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Fateme Ghiasi

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Khatam al anbia Hosp, Jame jam Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9815733169

Phone

+98 54 3322 0501

Email

f_ghiasi_p@zaums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Fateme Ghiasi

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of rehabilitation, Complex Pardis of Zahedan
University of medical Science, Khalij Fars Blv., Dr.
Hesabi Sq., Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9815733169

Phone

+98 54 3341 6708

Fax**Email**

f_ghiasi_p@zaums.ac.ir

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