Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

The effect of early mobilization on clinical index in patients with respiratory failure undergoing mechanical ventilation in intensive care units

Protocol summary

Study aim

Determination and comparison of respiratory indicators of patients with respiratory failure under ventilator before and after intervention in two groups of control and intervention. Determining and comparing the duration of mechanical ventilation of patients with respiratory failure under ventilator before and after the intervention in two groups of control and intervention.

Design

Randomized Control Trial(RCT) with control and parallel group

Settings and conduct

The research environment of ICU ward of Imam Khomeini Hospital is affiliated with Tehran University of Medical Sciences. Respiratory index of patients in the intervention group will be measured first and at the end of each day Other indicators, such as the duration of mechanical ventilation and the length of hospital stay in the ICU, will be collected in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria for this study included 48 hours after intubation and mechanical ventilation, age over 18 years and under 65 years, patients with RASS greater than -3 and less than 2, stable hemodynamic conditions with minimal dose of supportive drugs, Patients with PEEP <8, <60 FiO2, 89 <Spo2% and respiration rate of more than 12 and less than 30.

Intervention groups

The intervention designed for this study is a standard 4-level protocol. Measures taken at this level include changing the position every 2 hours, inactive movement of the joint area 3 times a day, and the patient should be placed in a fully sitting position for at least 2 times for 20 minutes. All second-level measures are also performed at levels 3 and 4.

Main outcome variables

Respiratory index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161124031068N4**
Registration date: **2020-05-21, 1399/03/01**
Registration timing: **prospective**

Last update: **2020-05-21, 1399/03/01**
Update count: **0**

Registration date

2020-05-21, 1399/03/01

Registrant information

Name

Maryam Esmaeili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6105 4402

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-19, 1399/03/30

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of early mobilization on clinical index in patients with respiratory failure undergoing mechanical ventilation in intensive care units

Public title
Effect of early mobilization on clinical index in respiratory failure

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Passing 48 hours after intubation and mechanical ventilation -3 < RASS < 2 Hemodynamic situation stability PEEP < 8 Fio2 < 60 Spo2 > 89 12 > RR > 30 60 < MAP > 110

Exclusion criteria:
Psychosomatic disorder Any mobility disfunction Acute cerebral strock BMI>40 Femour fracture After CPR

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into control and intervention groups based on the random allocation of double blocking. To do this, the 4 blocks will be selected so that they will belong to the letter A intervention group and the letter B control group. 6 probable states are written on separate cards and one number (from one to six) will be assigned to each card, then the numbers will be written on paper and randomly removed.Until the expected number of samples is completed. In this study, online randomization service (https://www.sealedenvelope.com/simple-randomiser/v1/lists) will be used for randomized block allocation.Allocation concealment will be done using closed envelopes, so that one letter is placed inside each envelope in the specified order, and then the envelope lid will be closed and provided to the researcher.

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 in Research, School of Nursing and Midwifery, and Faculty of Rehabilitation, Tehran

Street address
Nosrat St.,Tohid Sq.,Tehran,Iran

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2020-04-28, 1399/02/09

Ethics committee reference number
IR.TUMS.FNM.REC.1399.007

Health conditions studied

1

Description of health condition studied
Respiratory Failure

ICD-10 code
J96.9

ICD-10 code description
Respiratory failure, unspecified

Primary outcomes

1

Description
Respiratory index

Timepoint
Before the start, the end of the first day, the end of the second day, the end of the third day

Method of measurement
Arterial blood gas and monitoring system

Secondary outcomes

1

Description
Duration of hospital stay in ICU and duration of mechanical ventilation

Timepoint
Mechanical ventilation weaning and discharge from ICU

Method of measurement
Questionnaire

Intervention groups

1

Description

Intervention group:The intervention designed for this study is a standard 4-level protocol. In the first level, the range of motion of the joints is performed on non-conscious patients and five times on each joint. At the second level, the physiotherapy protocol begins.The patient must answer three of the commands so that the researcher realizes that she/he is ready to enter the next stage.Open your eyes, look at me, open your mouth and stick out your tongue, raise and lower your head, raise your eyebrows when you hear the number 5. If the patient responds to three of the researcher's five requests, his or her condition is appropriate for initiating physiotherapy. When the patient finds sufficient strength and alertness to participate in occupational therapy, he or she will be moved toward two active recipient approaches or active range of motion. They move from level 2 to 4.Measures taken at this level include changing the position every 2 hours, inactive movement of the joint area 3 times a day, and the patient should be placed in a fully sitting position for at least 2 times for 20 minutes.All second-level measures are also performed at levels 3 and 4. The upgrade from level 2 to 3 and from 3 to 4 depends on the score that the patient receives from the MRC criterion in terms of muscular strength in one attempt.A score of 3 out of 5 on the biceps is required to enter level 3 and a score of 3 out of 5 on the quadriceps is required to enter level 4. As the patient progresses, activities should focus on a variety of functions such as sitting on the edge of the bed, getting out of bed, sitting in a balanced position, and pre-starting exercises such as weight transfer on the legs or walking and moving. The implementation of this protocol in the form of interdisciplinary and team work with the cooperation of the members of this team will include a researcher, physiotherapist, physician in charge of ICU and assistant to the ward assistant.

Category

Rehabilitation

2

Description

Control group: In this study, the control group will receive the usual care of the ward. The usual care of the section under study in this study is to change the position once or twice in each shift.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomaini hospital

Full name of responsible person

Maryam Esmaeili

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Nosrat St., Tohid Sq., Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohamad Ali Sahraeian

Street address

sixth floor, Deputy of Research and Technology, Central University Organization, corner of Quds Street, Keshavarz Boulevard,

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Esmaeili

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work
Nursery
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data will be shared.
When the data will become available and for how long
starting 6 months after publication.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
There is no limitation.
From where data/document is obtainable
Email address.
What processes are involved for a request to access data/document
Documents will be sent via email after the work is completed and 6 months after the article is published.
Comments