

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Aug 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 FiO<sub>2</sub>, 89 <SpO<sub>2</sub>% 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)

##### Phone

+98 21 6105 4402

##### Email address

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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                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Scientific title</b>                       | The effect of early mobilization on clinical index in patients with respiratory failure undergoing mechanical ventilation in intensive care units                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Public title</b>                           | Effect of early mobilization on clinical index in respiratory failure                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Purpose</b>                                | Supportive                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Inclusion/Exclusion criteria</b>           | <p><b>Inclusion criteria:</b></p> <p>Passing 48 hours after intubation and mechanical ventilation -3 &lt; RASS &lt; 2 Hemodynamic situation stability PEEP &lt; 8 Fio2 &lt; 60 Spo2 &gt; 89 12 &gt; RR &gt; 30 60 &lt; MAP &gt; 110</p> <p><b>Exclusion criteria:</b></p> <p>Psychosomatic disorder Any mobility disfunction Acute cerebral strock BMI&gt;40 Femour fracture After CPR</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Age</b>                                    | From <b>18 years</b> old to <b>65 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Gender</b>                                 | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Phase</b>                                  | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Groups that have been masked</b>           | No information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Sample size</b>                            | Target sample size: <b>60</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Randomization (investigator's opinion)</b> | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Randomization description</b>              | <p>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 (<a href="https://www.sealedenvelope.com/simple-randomiser/v1/lists">https://www.sealedenvelope.com/simple-randomiser/v1/lists</a>) 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.</p> |
| <b>Blinding (investigator's opinion)</b>      | Not blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Blinding description</b>                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Placebo</b>                                | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Assignment</b>                             | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Other design features</b>                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Secondary Ids</b>                          | 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 khomaii hospital

##### Full name of responsible person

Maryam Esmaeili

##### Street address

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

##### City

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#### Province

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#### Postal code

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#### Phone

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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,

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733171

##### Phone

+98 21 8163 3685

##### Email

vcr@tums.ac.ir

#### 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

**Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Esmaeili

**Position**

Associate Professor, Tehran university of medical sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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**Position**

Associate professor, Tehran university of medical sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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**