

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Comparing the Effect of Physiotherapy of Limbs and Chest on Physiological Indices of Patients Admitted to Intensive Care Units (ICUs)

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Summary

This study aims at comparing the effect of physiotherapy of limbs and chest with that of routine physiotherapy procedures on the changes in physiological indices in patients hospitalized in ICUs. Inclusion criteria for the study include: over 18 years of age, informed consent of the patient's parents/guardian for participation in the research, at least 2 days of hospitalization in intensive care unit, having stable hemodynamics, and having GCS lower than seven and being under ventilator (intubate). Exclusion criteria are refusal of the patient's parents/guardian to continue the study, the incidence of severe reduction in left ventricular contractility (less than 30 percent) and the incidence of severe renal dysfunction (urine output less than 30cc/hr). In an interventional study, the subjects will be selected by convenience sampling and randomly divided into three groups (two intervention groups and one control group). The study population are the patients admitted to ICUs and the sample size is 90. After selecting the patients, chest physiotherapy will be carried out by the physiotherapist in the first intervention group and physiological indices (blood pressure, respiratory rate, and arterial oxygen saturation) will be checked before, during, 1 hour later, and 2 hours later. In the second intervention group, limb physiotherapy will be carried out by the physiotherapist and physiological indices are checked in the first group. In contrast, routine physiotherapy procedures of ICUs will be used for the patients in the control group and physiological indices are evaluated as in the two intervention groups. Finally, the results are analyzed by the statistician.

Last update:

Update count: **0**

#### Registration date

2015-12-24, 1394/10/03

#### Registrant information

##### Name

Mokhtar Mahmoudi

##### Name of organization / entity

Iran University Of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4435 5764

##### Email address

mokhtar.mahmoudi@arakmu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

This budget will be provided by Arak University of Medical Sciences.

#### Expected recruitment start date

2015-11-22, 1394/09/01

#### Expected recruitment end date

2016-02-20, 1394/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing the Effect of Physiotherapy of Limbs and Chest on Physiological Indices of Patients Admitted to Intensive Care Units (ICUs)

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015110921896N6**

Registration date: **2015-12-24, 1394/10/03**

## Public title

Comparing the Effect of Physiotherapy of Limbs and Chest on Physiological Indices of Patients Admitted to Intensive Care Units (ICUs)

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria: over 18 years of age, informed consent of the patient's parents/guardian for participation in the research; at least 2 days of hospitalization in intensive care unit, having stable hemodynamics; having GCS lower than seven and being under ventilator (intubated)  
Exclusion criteria: refusal of the patient's parents/guardian to continue the study; the incidence of severe reduction in left ventricular contractility (less than 30 percent); the incidence of severe renal dysfunction (urine output less than 30cc/hr)

## Age

From **18 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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 Arak University Of Medical Science

##### Street address

Sardasht Street, Arak University Of Medical Science, Arak

##### City

Arak

##### Postal code

#### Approval date

2015-09-14, 1394/06/23

#### Ethics committee reference number

IR.ARAKMU.REC.1394.179

## Health conditions studied

### 1

#### Description of health condition studied

limb and chest physiotherapy

#### ICD-10 code

Chapter XI

#### ICD-10 code description

Diseases of the musculoskeletal system and connective tissue

## Primary outcomes

### 1

#### Description

chest physiotherapy

#### Timepoint

1 hours ago, during, after 1 hours, after 2 hours

#### Method of measurement

evaluation of physiologic index

### 2

#### Description

limb physiotherapy

#### Timepoint

1 hours ago, during, after 1 hours, after 2 hours

#### Method of measurement

evaluation of physiologic index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

intervention group: in the first intervention group and physiological indices (blood pressure, respiratory rate, and arterial oxygen saturation) will be checked before, during, 1 hour later, and 2 hours later.

#### Category

Rehabilitation

### 2

#### Description

second intervention: In the second intervention group, limb physiotherapy will be carried out by the physiotherapist and physiological indices will be checked as in the first group.

#### Category

Treatment - Drugs

### 3

#### Description

control group: routine physiotherapy procedures of ICUs

will be used for the patients in the control group.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Amiralmomenin Training And Remedial Center

**Full name of responsible person**

Ms Hajian Leila

**Street address**

Amiralmomenin Hospita Center,Sardasht  
Street,Arak,Iran

**City**

Arak

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Arak University of  
Medical Sciences

**Full name of responsible person**

Dr Rafii Mohammad

**Street address**

College Of Nursing And Midwifery,Sardasht Street,  
Arak, Iran

**City**

Arak

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Arak University of Medical  
Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

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

College Of Nursing & Midwifery

**Full name of responsible person**

Mahmoudi Mokhtar

**Position**

Msc in Nursing

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

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*

**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*