

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

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 (intubated). 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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110921896N6**

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

Registration timing: **registered_while_recruiting**

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)

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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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