

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Study of the effect of passive walking -like Exercise on cardiac and respiratory parameters of patients admitted to intensive care units: Controlled Clinical Trial

Protocol summary

Study aim

Determining the effect of passive walking-like exercises on cardiac and respiratory parameters of patients admitted to intensive care units

Design

Clinical trial with control group, with parallel groups, without blinding, open-label, random with 50 patients. Used to randomize the blocking method with Allocation Random software.

Settings and conduct

The study in the intensive care unit, on patients' beds, the passive walking method is repeated 5 times a week for 2 weeks, each time for 20 minutes is performed. Due to the unavailability of the device, the simulated protocol is performed. Step 1 and 2: Flexion-extension of the right and then left thigh with a maximum range of 45 degrees at a speed of 30 times per minute for 10 minutes; Steps 3 and 4: Flexion-extension of the right knee and then left with a maximum range of motion of 60 degrees and dorsi-plantar flexion of the right ankle and then left with a maximum range of motion of 10 and 15 degrees simultaneously at speed of 30 times per minute, for 10 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: at least 18, connected to a mechanical ventilation hemodynamic and cardiac stability, confirmation of the treating physician, written consent: Exclusion criteria: increased intracranial pressure, having a neuromuscular disease, spinal cord injury, cardiopulmonary arrest, fractures in the lower limbs

Intervention groups

For the control group, routine care and for the intervention group, in addition to routine care, passive walking exercises are performed

Main outcome variables

Shock index: MAP: Airway resistance: Compliance: PaO₂ / FiO₂: Peak pressure: SBP and DBP: HR: respiration rate:

Saturation of Peripheral Oxygen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211119053107N1**

Registration date: **2022-01-09, 1400/10/19**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**

Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Yosra Karimi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-31, 1400/10/10

Expected recruitment end date

2022-03-22, 1401/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of passive walking -like Exercise on cardiac and respiratory parameters of patients admitted to intensive care units: Controlled Clinical Trial

Public title

Study of the effect of passive walking exercises on the cardiac and respiratory system of patients admitted to intensive care units

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

At least 18 years old Connecting to a mechanical ventilation that is at least 24 hours old Hemodynamic and cardiac stability Confirmation of the treating physician that the patient is not prohibited from performing the protocol Obtaining written consent from the patient's legal guardian

Exclusion criteria:

Increasing of intracranial pressure Having a history of previous or rapidly growing neuromuscular disease Spinal cord injury Cardiopulmonary arrest Having fractures in the pelvis and lower limbs

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The first step of creating a random sequence: In this study, the limited randomization method of block randomization will be used. In this two-group experiment, we will have four blocks consisting of two participants in the intervention group and two participants in the control group. There will be six different modes in these four blocks; So we prepare six cards as follows: 3. PMPM 2. PMMP 1. PPMM 4. MPMP 6. MPPM 5. MMPP Given that the number of patients studied is estimated at 50, we remove 13 of the above cards by replacement. The second step of hiding accident allocation: The selection of cards will be determined using a table of random numbers in Software Allocation Random. Blocking and allocation sequencing for concealment will be done by the person not involved in the research. Then, based on the obtained blocks and allocation sequence, they will be divided into intervention and control groups.

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 Kermanshah University of Medical Sciences

Street address

Deputy of Research and Technology; Building No. 2 of Medical Sciences; Shahid Beheshti Boulevard

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Province

Kermanshah

Postal code

6714673159

Approval date

2021-12-14, 1400/09/23

Ethics committee reference number

IR.KUMS.REC.1400.605

Health conditions studied**1****Description of health condition studied**

Respiratory failure

ICD-10 code

J96.9

ICD-10 code description

Respiratory failure, unspecified

2**Description of health condition studied**

Heart failure

ICD-10 code

I50.9

ICD-10 code description

Heart failure, unspecified

Primary outcomes**1****Description**

Average shock index

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

Shock Index=(Heart Rate)/(Systolic Blood Pressure)-

Physiological indicators(Cardiorespiratory monitoring)

2

Description

Average of mean arterial pressure

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

Mean arterial pressure = (systole + 2 diastole) / 3 _
Physiological indicators(pressure indicator)

3

Description

Average airway resistance

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

Airway resistance= tail end wedge pressure - alveolar_
ventilator pressure_ ventilator

4

Description

Average compliance

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

Compliance = volume change / pressure change_
ventilator

5

Description

Average relative arterial oxygen pressure to percentage of tail oxygen

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

PaO₂ / FiO₂=Relative arterial oxygen pressure / percentage of tail oxygen - a tool for measuring
_Physiological indicators(Cardiorespiratory monitoring)

6

Description

Average peak inspiratory pressure

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

ventilator

7

Description

Average systolic and diastolic blood pressure

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

Physiological indicators(pressure indicator)

8

Description

Average heart rate

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

Physiological indicators(Cardiorespiratory monitoring)

9

Description

Average respiration rate

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

Physiological indicators(Cardiorespiratory monitoring)

10

Description

Average percentage of peripheral blood oxygen saturation

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

Physiological indicators(Cardiorespiratory monitoring)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, in addition to routine care, it will perform passive walking exercises. The passive walking method is repeated 5 times a week for 2 weeks and 20 minutes of practice each time. Walking involves moving the hip, knee and ankle joints. Due to the unavailability of the device and the high cost of providing the device, the simulated walking of the protocol is performed as follows: Step 1: Flexion-extension of the right thigh with a maximum range of 45 degrees at a speed of 30 times per minute , Runs for 10 minutes; Second stage: Flexion-extension of the left thigh is practiced similarly to the right thigh; Runs 30 times per minute for 10 minutes; Step 4: According to the third step, flexion-knee extension and dorsi-plantar flexion of the left ankle are practiced; The researcher goes to the intensive care unit and on the patient's bed, performs this procedure for 2 weeks (5 sessions per week) while the patient is lying down and

about 30 degrees above the head.

Category

Treatment - Other

2**Description**

Control group: do not receive intervention, receive routine care.

Category

Treatment - Other

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

Imam Ali hospital

Full name of responsible person

Dr Alireza Abdi

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2**Recruitment center****Name of recruitment center**

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3**Recruitment center****Name of recruitment center**

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4**Recruitment center****Name of recruitment center**

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

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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

Kermanshah 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

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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