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-lable, 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 1and 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
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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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Shahid Beheshti Boulevard

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2

Recruitment center

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Ayatollah Taleghani hospital

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3

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Recruitment center

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Sponsors / Funding sources

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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

Person responsible for general inquiries

Contact
Name of organization / entity
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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