

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of passive movement of lower extremity on hemodynamic and ventilation parameters in patients under ventilator in intensive care unit

Protocol summary

Summary

The aim of this clinical trial study is to determine of the effect of passive movement of lower extremity on hemodynamic and ventilation parameters in patients under ventilator in intensive care unit. 64 patients under ventilator with lack of deep vein thrombosis, fracture or amputation of lower limbs; and spine injury who admitted to the intensive care unit, will select through convenience sampling and assignee to the intervention group and control group(with equal numbers) using block random allocation. At baseline, hemodynamic parameters such as systolic blood pressure, diastolic blood pressure, mean arterial pressure, arterial oxygen saturation, pulse rate, pulse pressure and temperature, and ventilation parameters such as respiratory rate, respiratory tidal volume, and respiratory minute volume of all samples will be record. While the control group will receive the routine treatment and cares, in the intervention group, in addition to routine treatment and cares, the nurses will do, protocol passive movement of the lower extremity consist of each leg rising, high and down and rotational movements on the ankles, bend and straighten of the knee, flexion and extension of hip joints for patients who are at semi setting in angle of 30 degrees during 22 minutes. Above hemodynamic and ventilation parameters will record Immediately, 2 hour, 6 hour,12 hour, and one day after passive movement of lower extremity in each study group, and data will analyze and compare.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041727444N1**

Registration date: **2016-09-04, 1395/06/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-04, 1395/06/14

Registrant information

Name

Rahman Rezaei kia

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Yasuj University of Medical Science

Expected recruitment start date

2016-05-14, 1395/02/25

Expected recruitment end date

2016-06-14, 1395/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of passive movement of lower extremity on hemodynamic and ventilation parameters in patients under ventilator in intensive care unit

Public title

Impact of movement on patient's physiological indices

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: lack of deep vein thrombosis of lower extremities; lack of active rheumatoid arthritis; lack of fracture or amputation of lower limbs; absence of congenital anomalies in lower extremities; lack of congestive heart failure; Lack of spine injury; completion of written informed consent by legal guardian; and exclusion criteria will :Lack of legal guardian's motivation for continue the cooperation; exacerbation of patient's condition that continuation of intervention won't possible; patient's transfer to another Hospital; incidence of dangerous dysrhythmia; incidence of symptoms of intracranial pressure increase; death of patient

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The patients as research units will select from study population who will eligible according inclusion criteria using convenience sampling, then assignee to intervention group and control group by block random allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Deputy of research and technology, Yasuj University of Medical Science, Shahid Motahari Blvd.

City

Yasuj

Postal code

7591741417

Approval date

2016-04-18, 1395/01/30

Ethics committee reference number

IR.YUMS.REC.1395.4

Health conditions studied

1

Description of health condition studied

patients under mechanical ventilation

ICD-10 code

Z51.9

ICD-10 code description

Medical care, unspecified

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before intervention; immediately; 2 hour after passive movement of lower extremity; 6 hour, 12 hour, and one day after intervention

Method of measurement

According to mmhg using Saadat vital sign monitoring equipment (saadat S740) made in iran

2

Description

Diastolic blood pressure

Timepoint

Before intervention; immediately; 2 hour after passive movement of lower extremity; 6 hour, 12 hour, and one day after intervention

Method of measurement

According to mmhg using Saadat vital sign monitoring equipment (saadat S740) made in iran

3

Description

Mean arterial blood pressure

Timepoint

At the beBefore intervention; immediately; 2 hour after passive movement of lower extremity; 6 hour, 12 hour, and one day after interventinginning of study

Method of measurement

According to mmhg using Saadat vital sign monitoring equipment (saadat S740) made in iran and insert amounts in formula: [(Systolic blood pressure+2 Diastolic blood pressure)/3]

4

Description

O2 saturation

Timepoint

Before intervention; immediately; 2 hour after passive movement of lower extremity; 6 hour, 12 hour, and one day after intervention

Method of measurement

According to percentage using Saadat vital sign monitoring equipment (saadat S740) made in iran

5**Description**

Pulse rate

Timepoint

Before intervention; immediately; 2 hour after passive movement of lower extremity; 6 hour, 12 hour, and one day after intervention

Method of measurement

According to number per minute using Saadat vital sign monitoring equipment (saadat S740) made in iran

6**Description**

Pulse pressure

Timepoint

Before intervention; immediately; 2 hour after passive movement of lower extremity; 6 hour, 12 hour, and one day after intervention

Method of measurement

According to mmhg using Saadat vital sign monitoring equipment (saadat S740) made in iran and insert amounts in formula: (Systolic blood pressure- Diastolic blood pressure)

7**Description**

Temperature

Timepoint

Before intervention; immediately; 2 hour after passive movement of lower extremity; 6 hour, 12 hour, and one day after intervention

Method of measurement

According to centigrade using Saadat vital sign monitoring equipment (saadat S740) made in iran

8**Description**

Respiration rate

Timepoint

Before intervention; immediately; 2 hour after passive movement of lower extremity; 6 hour, 12 hour, and one day after intervention

Method of measurement

According to number per minute using Drager ventilator model Evita2 made in Germany

9**Description**

Respiratory tidal volume

Timepoint

Before intervention; immediately; 2 hour after passive movement of lower extremity; 6 hour, 12 hour, and one day after intervention

Method of measurement

According to ml using Drager ventilator model Evita2 made in Germany

10**Description**

Respiratory minute volume

Timepoint

Before intervention; immediately; 2 hour after passive movement of lower extremity; 6 hour, 12 hour, and one day after intervention

Method of measurement

According to ml using Drager ventilator model Evita2 made in Germany

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Applying protocol of passive movement of lower extremity consist of raising each legs, up and down and rotational movements at the ankles, flexion and extension of each knees and hip joints in addition to receiving routine treatment and usual care

Category

Treatment - Other

2**Description**

Control group:giving routine treatment and usual care, but not giving research interventions

Category

Other

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

Shahid Beheshti Hospital

Full name of responsible person

Dr. Seyed Zaker Saieedinejad

Street address

Shahid Montazeri Street, Yasuj

City

Yasuj

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

Imam Sajjad Hospital

Full name of responsible person

Dr. Farzad Vafaie

Street address

Shahid Dr.Jalil Street, Yasuj
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Yasuj

3

Recruitment center

Name of recruitment center
Shahid Rajaie Hospital
Full name of responsible person
Dr. Hayedeh Hafez Quran
Street address
Shafa Square, Parastar Street, Gachsaran
City
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4

Recruitment center

Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr. Amir Molaie
Street address
Sepah Street, Dehdasht
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5

Recruitment center

Name of recruitment center
Namazi Hospital
Full name of responsible person
Dr. Reza Jouybar
Street address
Namazi Square, Zand Street , Shiraz
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6

Recruitment center

Name of recruitment center
Shahid Faghihi(Saadi) Hospital
Full name of responsible person
Dr. Peyman Petramfar
Street address
Zand Street, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chanellor for research of Yasuj University of
Medical Sciences
Full name of responsible person
Dr. Seyed Abdmohammad Mousavi
Street address

Vice Chancellor for research , Yasuj University of
Medical Science, Shahid Motahari Blvd.

City
Yasuj

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chanellor for research of Yasuj 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

Yasuj University of Medical Sciences

Full name of responsible person

Dr. Mohammad Zoladl

Position

PhD of psychiatric nursing ; Associate Professor

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Shahla Najafi Dolatabad

Position

Ms of medical surgical nursing, faculty
member(lecturer)

Other areas of specialty/work

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rahman.rezaei93@gmail.com

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

Yasuj University of Medical Sciences

Full name of responsible person

Rahman Rezaeikia

Position

Ms student of medical surgical nursing

Other areas of specialty/work**Street address**

Faulty of nursing and midwifery of Yasuj University of
Medical Science, Shahid Dr.Jalil Street

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