

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The study of the simultaneous effect of therapeutic motion and heat therapy using Vanda apparatus on the extent of motion and muscle stiffness of patients in the intensive care unit

Protocol summary

Study aim

The study of the simultaneous effect of therapeutic motion and heat therapy using Vanda apparatus on the extent of motion and muscle stiffness of patients in the intensive care unit

Design

Two arms parallel group randomized trial, supportive purpose with 38 patients

Settings and conduct

In this research, which is an interventional study, 38 patients who were admitted to the ICU of Shahid Beheshti Hospital of Kashan and who were discharged after reaching a steady state status were selected. Then, if the conditions for entering the study are met, the method of doing work will be explained to relatives of the patient. If the fellows are willing to conduct a study on their patients at home, written consent will be provided upon admission to the study and prior to randomization. Then, the patients were divided into two groups of 19 control and Simple randomization were done. These patients will be examined for 21 days. Before any intervention, the environmental conditions in terms of light, temperature, and sound are identical in both groups. It should be noted that the researcher will not perform any additional interventions other than the function of the device in the test group, and also a prohibition on what is done by the attendants at home, except for lack of massage in the lower limb of the test group, and in the control group no action is taken and only Variables are measured at specific times. To carry out heat therapy, the device twice a day for twenty minutes to slowly warm the patient's lower extremity to achieve its therapeutic effect.

Participants/Inclusion and exclusion criteria

1 - Patients who have been admitted to ICU and need Home Care due to a general condition. 2 - Patient Family Satisfaction. 3 - Good general condition for the patient.

Intervention groups

Controlling: Absence of simultaneous motion and heat therapy using the Vanda machine Intervention: Recipient of simultaneous motion and thermal therapy using the Vanda machine

Main outcome variables

Motion Therapy, Heat Therapy, Motion and muscle stiffness, Patients in intensive care units

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180213038713N1**

Registration date: **2018-05-14, 1397/02/24**

Registration timing: **retrospective**

Last update: **2018-05-14, 1397/02/24**

Update count: **0**

Registration date

2018-05-14, 1397/02/24

Registrant information

Name

Habibolah Dashti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2290

Email address

habibdasht@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-24, 1395/02/05
Expected recruitment end date
 2017-04-25, 1396/02/05
Actual recruitment start date
 2016-04-24, 1395/02/05
Actual recruitment end date
 2017-04-25, 1396/02/05
Trial completion date
 empty

Scientific title
 The study of the simultaneous effect of therapeutic motion and heat therapy using Vanda apparatus on the extent of motion and muscle stiffness of patients in the intensive care unit

Public title
 The study of the simultaneous effect of therapeutic motion and heat therapy using Vanda apparatus on the extent of motion and muscle stiffness of patients in the intensive care unit

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients who have been admitted to ICU and need Home Care due to a general condition. Patient Family Satisfaction. Good general condition for the patient.
Exclusion criteria:
 Congenital Musculoskeletal Disorders Acute cardiovascular disease

Age
 From **18 years** old to **70 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **38**
 Actual sample size reached: **38**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Simple randomization of coin toss

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
 Tehran university of medical sciences, Imam khomeini hospital complex
Street address
 Kershavarz Blvrd
City
 Tehran
Province
 Tehran
Postal code
 1419733141
Approval date
 2018-01-10, 1396/10/20
Ethics committee reference number
 IR.TUMS.IKHC.REC.1396.4188

Health conditions studied

1
Description of health condition studied
 Muscle stiffness in patients of intensive care units
ICD-10 code
 (M00-M99)
ICD-10 code description
 Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1
Description
 Lower limb muscles length
Timepoint
 The beginning of the study and 21 days later
Method of measurement
 Standard goniometer

Secondary outcomes

1
Description
 Changes in lower limb edema
Timepoint
 The beginning of the study and 21 days later
Method of measurement
 Standard goniometer

Intervention groups

1
Description
 Intervention group: Patients after motion and heat therapy
Category
 Treatment - Devices

2

Description

Control group: Patients without motion and heatTherapy

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Shahid Beheshti Hospital

Full name of responsible person

mokhtari rasoul

Street address

3km after Ravand Road - Doctor Blvd.

City

isfahan

Province

Isfahan

Postal code

81151/87159

Phone

+98 31 3452 1109

Email

mokhtarirasul@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Habobollah Dashti

Street address

Keshavarz blvd

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Tehran

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habibdasht@gmail.com

Grant name

Grant code / Reference number

96-01-205-31895

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Habibolah Dashti

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

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Fax**Email**

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document**When the data will become available and for how long****To whom data/document is available****Under which criteria data/document could be used****From where data/document is obtainable****What processes are involved for a request to access data/document****Comments**