

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of rehabilitation program on intensive care unit acquired weakness

Protocol summary

Study aim

Determining the implementation of rehabilitation in the Intensive care unit weakness

Design

This study is a two-group clinical trial. a random allocation method with blocks of 4 of equal size and a combination of even numbers for the intervention group and odd numbers for the control group will be allocated into two control and intervention groups. For this purpose, a table of odd and even numbers has been prepared without a specific pattern and order. The sample size of each group is 30 people.

Settings and conduct

In the intensive care unit of Imam Khomeini hospital, physiotherapy will be performed for 14 days.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study include: patients aged 18 to 60 years, hospitalized in the intensive care unit, a written order from the doctor to perform rehabilitation, written consent from the patient or his/her guardian, level of consciousness score based on the Glasgow Coma Scale above 10, stable hemodynamic status, BMI under 35 kg/m2, absence of underlying neuromuscular diseases such as myasthenia gravis, absence of spine damage The exclusion criteria include: death of the patient, entering the acute stages of the disease, instability of hemodynamic conditions, being diagnosed with deep vein thrombosis , unwillingness to continue cooperation in the physical rehabilitation program on behalf of the patient or his family.

Intervention groups

In the control group, patients who meet the entry criteria complete the study tools after obtaining informed consent. In the intervention group, after obtaining informed consent, the study tools are completed, then the physical therapy of the organs is performed for 14 days, twice a day for 20 minutes. In case of transfer to the ward, the intervention will continue until the end of the 14th day.

Main outcome variables

Muscle weakness and strength, deep tendon reflex

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190913044760N2**

Registration date: **2023-07-29, 1402/05/07**

Registration timing: **retrospective**

Last update: **2023-07-29, 1402/05/07**

Update count: **0**

Registration date

2023-07-29, 1402/05/07

Registrant information

Name

Zahra Abbbasi Dolatabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

2023-04-09, 1402/01/20

Actual recruitment end date

2023-07-23, 1402/05/01

Trial completion date

2023-07-23, 1402/05/01

Scientific title

The effect of rehabilitation program on intensive care unit acquired weakness

Public title

The effect of rehabilitation program on intensive care unit acquired weakness

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

age between 18 to 60 years written consent from patient or her/his guardian admission to the intensive care unite
Body mass index Below 35 kg/m2 written doctor`s order to perform rehabilitation level of consciousness based on glasgow coma test above 10 stable hemodynamic status
Absence of background diseases such as myasthenia gravis no damage to the spine

Exclusion criteria:

death of the patient Entering the acute stages of the disease Hemodynamic instability diagnosed with Deep vein thrombosis Unwillingness to cooperate on behalf of the patient or her/his guardian

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated to two control and intervention groups using the block random allocation method with blocks of 4 of equal size and a combination of even numbers for the intervention group and odd numbers for the control group. For this purpose, a table of odd and even numbers has been prepared without a specific pattern and order, and thus the allocation method is determined.

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 Imam Khomeini Hospital of Tehran University of Medical Sciences

Street address

58 / 5,000 Translation results Keshavarz Blvd., Doctor Gharib St., Imam Khomeini Hospital Complex

City

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Province

Tehran

Postal code

1419733141

Approval date

2022-11-15, 1401/08/24

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.216

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

intensive care unit acquired weakness

ICD-10 code

G72.81

ICD-10 code description

Critical illness myopathy

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

Index of muscle weakness, muscle strength and deep tendon`s reflexe

Timepoint

Before and after intervention

Method of measurement

Using the Medical Research Council questionnaire for muscle weakness (MRC), which measures the flexion and extension movement of 6 muscle groups as points and is scored from 0 to 60, and a score below 48 is considered muscle weakness.

2**Description**

The effect of rehabilitation program on muscle strength

Timepoint

Before and after intervention

Method of measurement

Using a tool called a handgrip dynamometer is used to measure hand strength based on kilograms.

Secondary outcomes

1

Description

The effect of rehabilitation program on deep tendon reflex

Timepoint

Before and after intervention

Method of measurement

Using a questionnaire called DTR, the tendon reflex of the biceps, triceps, brachioradialis, knee and ankle muscles is measured from 0 to +4.

Intervention groups

1

Description

Control group: In the intensive care unit of Imam Khomeini hospital, as a control, patients and their guardians are asked to complete the study tools after obtaining informed consent. The above process will continue until reaching the determined sample size.

Category

Rehabilitation

2

Description

Intervention group: In the Intensive care unit of Imam Khomeini Hospital, the instrument under study is completed after obtaining informed consent from the patients who meet the entry criteria or their guardians. Then the physical therapy of the organs is performed for 14 days, twice a day (10 AM- 4PM) for 20 minutes under the supervision of a physiotherapist. The study tool will be completed again at the end of the 14th day. In case of transfer to the ward, the intervention will continue until the end of the 14th day.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital complex

Full name of responsible person

Moahammad Amin Matufi Azar

Street address

Dr. gharib street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohamadali Sahraiean

Street address

Sixth floor, Vice Chancellor for Research and Technology, Central University Organization, corner of Quds Street, Keshavarz Boulevard.

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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

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

Mohammad Amin Matufi Azar

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Medical surgical nursing

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Person responsible for updating data

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Name of organization / entity

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All unidentifiable data can be provided if required

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

All researchers working in scientific institutes and universities who send requests

Under which criteria data/document could be used

The data can be used in accordance with copyright law and for further research in this field

From where data/document is obtainable

Send an email to Mr.Mohammad Amin Matufi Azar at amin76tums@gmail.com

What processes are involved for a request to access data/document

After reviewing the application and the applicant's conditions, if approved, the data will be sent within a month.

Comments