

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Design, Manufacture and production of rehabilitation aid belt for Neurological Patients

Protocol summary

Study aim

Checking the level of satisfaction of physiotherapists after using the manufactured product

Design

Clinical trial with intervention group on 20 patients

Settings and conduct

This study will be conducted in Kausar Medical Research Training Center located in Semnan city. During this study, neurological patients admitted to the hospital who need to be set up and rehabilitated will be moved and carried by the physiotherapist in a safe and comfortable manner, and finally the level of satisfaction will be measured.

Participants/Inclusion and exclusion criteria

Conditions for entering patients: 1) Age 18 to 60 years of both sexes 2) Medical condition with stable cardiopulmonary vital signs 3) The state of consciousness of the patient should be 13 or higher on the Glasgow Coma Scale. 4) The request of the attending physician to start the patient 5) Patients with stable neurological conditions 6) Normal body mass index (19 to 25) 7) Willingness of the patient in order to start 8) Verbal communication by the patient - Patient discharge conditions: 1) Patients with acute or chronic back pain that interferes with their starting. 2) spinal canal stenosis 3) spine and hip surgery in the last 3 months 4) Non-cooperation of the patient in order to start 5) Severe edema of the lower limbs

Intervention groups

Neurological patients who need to be set up and rehabilitated who are hospitalized in the hospital wards are set up by the physiotherapist with the help of the manufactured product during the rehabilitation period.

Main outcome variables

Checking the level of satisfaction using a researcher-made questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230712058751N1**

Registration date: **2023-08-18, 1402/05/27**

Registration timing: **prospective**

Last update: **2023-08-18, 1402/05/27**

Update count: **0**

Registration date

2023-08-18, 1402/05/27

Registrant information

Name

Parisa Arzani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-09, 1402/06/18

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, Manufacture and production of rehabilitation aid belt for Neurological Patients		Province Semnan Postal code 3614773943 Approval date 2023-06-25, 1402/04/04 Ethics committee reference number IR.SEMUMS.REC.1402.076
Public title	Design, Manufacture and production of rehabilitation aid belt for Neurological Patients	
Purpose	Supportive	
Inclusion/Exclusion criteria	Inclusion criteria: Age 18 to 60 years of both sexes Medical condition with stable cardiopulmonary vital signs The state of consciousness of the patient should be 13 or higher on the Glasgow Coma Scale. The request of the attending physician to start the patient Patients with stable neurological conditions Normal body mass index Willingness of the patient in order to start Verbal communication by the patient Exclusion criteria: Patients with acute or chronic low back pain that interferes with starting. Spinal stenosis Spine and hip surgery in the last 3 months Non-cooperation of the patient in order to start Severe edema of the lower limbs	
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: 20	
Randomization (investigator's opinion)	N/A	
Randomization description		
Blinding (investigator's opinion)	Not blinded	
Blinding description		
Placebo	Not used	
Assignment	Single	
Other design features		
Secondary Ids	empty	
Ethics committees		
<u>1</u>		
Ethics committee		
Name of ethics committee	Research Ethics Committees of Semnan University Of Medical Sciences and Health Services	
Street address	Semnan university of medical sciences complex, Physiotherapy department	
City	Semnan	
		Health conditions studied <u>1</u> Description of health condition studied stroke ICD-10 code G46.4 ICD-10 code description Cerebellar stroke syndrome <u>2</u> Description of health condition studied Parkinson ICD-10 code G20 ICD-10 code description Parkinson's disease <u>3</u> Description of health condition studied multiple sclerosis ICD-10 code G35 ICD-10 code description Multiple sclerosis
		Primary outcomes
		<u>1</u> Description Checking the level of satisfaction of physiotherapists or using a researcher-made questionnaire Timepoint 21 days after the intervention Method of measurement Questionnaire
		Secondary outcomes
		empty
		Intervention groups
		<u>1</u> Description Intervention group: Treatment in the intervention group will include the use of a support belt produced for the safe and comfortable transportation of patients who

need to be set up. The patient, under the supervision of the physiotherapist, will be moved and transferred during the day with the help of the produced belt with the aim of starting and rehabilitation in the hospital.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kausar Semnan Medical Research Training Center

Full name of responsible person

Javad Hadadi

Street address

Kausar educational research and treatment center,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Majid Mirmohammadkhani

Street address

Basij Blvd., Semnan University of Medical Sciences
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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Javad Hadadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Parisa Arzani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available