Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
+98 23 3365 4181

Email address
parisa_arzani@semums.ac.ir

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

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

1

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
Province
Semnan
Postal code
3614773943
Approval date
2023-06-25, 1402/04/04
Ethics committee reference number
IR.SEMUMS.REC.1402.076

Health conditions studied

1

Description of health condition studied
stroke
ICD-10 code
G46.4
ICD-10 code description
Cerebellar stroke syndrome

2

Description of health condition studied
Parkinson
ICD-10 code
G20
ICD-10 code description
Parkinson's disease

3

Description of health condition studied
multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

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

1

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, Golestan town, Semnan, Semnan Province, Iran

City

semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3142 0115

Fax

Email

kosarhos@semums.ac.ir

Web page address

https://kosarhos.semums.ac.ir/

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 and Health Services Headquarters, Research and Technology Vice-Chancellor

City

semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Fax

+98 23 3344 8999

Email

majidmirmohammadkhani@yahoo.com

Web page address

https://rtvc.semums.ac.ir/%D8%AF%D8%B1%D8%A8%D8%A7%D8%B1%D9%87-%D9%85%D8%B9%D8%A7%D9%88%D9%86-%D8%AA%D8%AD%D9%82%DB%8C%D9%82%D8%A7%D8%AA-%D9%88-%D9%81%D9%86%D8%A7%D9%88%D8%B1%DB%8C

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

Street address

Farhangian settlement, Farhang 11, No. 11

City

Jajarm

Province

North Khorasan

Postal code

9441663667

Phone

+98 58 3227 9058

Email

hadadi1376@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parisa Arzani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Semnan university of medical sciences complex, physiotherapy complex

City

Semnan

Province

Semnan

Postal code

7394336147

Phone

+98 21 5102 5345

Email

Parisa_arzani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parisa arzani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Semnan university of medical sciences complex, Physiotherapy depatment

City

Semnan

Province

Semnan

Postal code

7394336147

Phone

+98 21 5102 5345

Email

Parisa_arzani@yahoo.com

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