

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Assessment the effect of The Heel Protective Device on the incidence and severity of pressure ulcer in elderly hospitalized patients with lower limbs fracture

#### Protocol summary

##### Study aim

Determining the effect of using heel support device on reducing the incidence and severity of pressure ulcers in the elderly with a lower limb fracture

##### Design

Clinical trials with a control group, non - blindness, randomized in Permuted block method

##### Settings and conduct

the research community of the elderly is a way of lower organ fracture, which is in the orthopedic parts of the Kamyab hospital. After selecting the Individuals who have entrance criteria, samples will be divided randomly into two groups of intervention and control groups. The intervention group will be used by heels supporting the patient's legs and reducing the pressure applied on the heel of the leg for three days. The heel support device will be made and used during the study. In the control group, routine actions will be performed, as it will be used from a pillow or roll blanket underneath the patient's leg and will be checked on a daily basis using a checklist of skin health assessment.

##### Participants/Inclusion and exclusion criteria

AGE more than 60 - unilateral lower limb fracture- informed consent of participating in the study- consciousness - the lack of acute problems - the absence of acute diseases - braden scores less than 16 - lack of a sustained and traumatic brain injury in the lower limb

##### Intervention groups

intervention group: The mechanism made by the heel supporting the heel on the heels of the patient's legs and the reduction of pressure applied on the heel to check the incidence and severity of the pressure wound will be used for three days. control group: Routine actions are carried out, so that it will be used for three days from a pillow or roll blanket underneath the calf's leg.

##### Main outcome variables

the incidence and the severity of the heel pressure ulcer

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200727048225N1**

Registration date: **2020-10-24, 1399/08/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-10-24, 1399/08/03**

Update count: **0**

##### Registration date

2020-10-24, 1399/08/03

##### Registrant information

##### Name

Saeedeh Mohammadi Saber

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3256 8674

##### Email address

mohammadis971@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-22, 1399/08/01

##### Expected recruitment end date

2021-02-19, 1399/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Assessment the effect of The Heel Protective Device on the incidence and severity of pressure ulcer in elderly hospitalized patients with lower limbs fracture

## Public title

Assessment the effect of The Heel Protective Device on the incidence of pressure ulcer

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age over 60 years Unilateral lower limb fracture informed consent to participate in research

### Exclusion criteria:

cognitive problems - Absence of - - Absence of acute diseases Braden score more than 16 pressure and traumatic ulcer in fractured lower limb

## Age

From **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Permuted block method In our study, we will use the random allocation of the random - block or permutation method to ensure that exactly equal numbers of participants are entered into the category of intervention and control. Each block size can be 5, 10, 16 to 20. In this way, intervention is given to the first block and routine maintenance to the second and again the first type to a third block and so on. The randomization benefits of the block are that the balance of the number of participants in each group is guaranteed. The number of people in each group will never exceed half the number of people per block. The disadvantages of this type of randomizations are that statistical analysis in this type of segmentation is more complex and there is also a foreseeable danger that there is no difficulty in identifying the use of the vehicle, and the results will be reliable.

## 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 Mashhad University of Medical Sciences

##### Street address

Daneshgah street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91388-13944

#### Approval date

2020-08-04, 1399/05/14

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1399.041

## Health conditions studied

### 1

#### Description of health condition studied

the heel pressure ulcer

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

the incidence of the heel pressure ulcer

#### Timepoint

before the intervention and for 3 days during the intervention

#### Method of measurement

Skin health assessment checklist (based on EPUAP pressure ulcer classification system)

### 2

#### Description

severity of the heel pressure ulcer

#### Timepoint

before the intervention and for 3 days during the intervention

#### Method of measurement

PUSH questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: in the intervention group the vehicle's supporting vehicle will be used for three days, and during this period it will be done for ten minutes for patients by caregivers or nurse. During one or two shifts the researcher will take two hours for ten minutes, ensuring that it will be reassured by either cell nurse or nurse. During the intervention of each day the pressure wound or the severity of the pressure wound in the soles of the foot and leg of the leg are examined using a check list of skin health assessment (redness, itching, and burn), as well as any allergy signs (redness, itching and burning), and change position with ease of use of the use of heels supporting heels and inclination to continue taking part in the study

**Category**

Prevention

**2****Description**

Control group: Routine actions will be performed, so that it will be used for three days from a pillow or roll blanket underneath the calf's leg.

**Category**

Prevention

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

Shahid Kamyab hospital

**Full name of responsible person**

Alireza mahmoudi gharaee

**Street address**

Fadaeeiane Eslam Ave.

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Daneshgah street

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tafaghodiM@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Saeedeh Mohammadi Saber

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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Nakhrisi Ave., Shahid kamyab hospital

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9156913111

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mohammadis971@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Esmaelzadeh

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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University St., Duktora Crossroads, School of Nursing and Midwifery, Mashhad University of Medical Sciences

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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**

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**

Yes - There is 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

**Title and more details about the data/document**

Only part of the data may be shared after identifying those related to the main outcome

**When the data will become available and for how long**

The beginning of the access period is 6 months after the results are published.

**To whom data/document is available**

Access is available only for practitioners working in academic and academic institutions

**Under which criteria data/document could be used**

The only analyses used in the study are allowed to be delivered on the data delivered

**From where data/document is obtainable**

mohammadis971@mums.ac.ir

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

The data will be contacted by e - mail, and the relevant demand for e - mail is called the request and call number

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Saeedeh Mohammadi Saber

**Position**

Master Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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