

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of follow-up prevention or these of heel pressure ulcer, drop foot, and pelvic rotation in patients coma or low alertness intensive care unit (ICU) Semnan kowsar hospital

Protocol summary

Study aim

The effect of follow-up prevention or these of heel pressure ulcer, drop foot, and pelvic rotation in patients coma or low alertness intensive care unit (ICU) Semnan kowsar hospital

Design

Clinical trials with control group, with parallel groups, randomized, without control with placebo, single center trial. Sample size was 60 patients (2 groups of 30 control and intervention).

Settings and conduct

Kowsar hospital's intensive care unit in Semnan. Heel pressure ulcer orthoses are used for 30 patient (Unconscious or with low alertness) admitted to the intensive care unit of Kowsar Hospital in Semnan for 7 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 20-70 years old; Patients with Diabetic Heel Wounds; Patients with heel soft tissue injuries. Exclusion criteria: Patient dissatisfaction.

Intervention groups

Control group: Only for comparison with intervention group, no treatment is performed. Intervention group: Heel pressure ulcer orthoses are used for patients (Unconscious or with low alertness) admitted to the intensive care unit of Kowsar Hospital in Semnan for 7 days.

Main outcome variables

Degree of hip rotation; Heel pressure ulcers.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N45**
Registration date: **2019-11-10, 1398/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-10, 1398/08/19**

Update count: **0**

Registration date

2019-11-10, 1398/08/19

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

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+98 23 3345 1336

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are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-16, 1398/04/25

Expected recruitment end date

2020-07-15, 1399/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of follow-up prevention or these of heel pressure ulcer, drop foot, and pelvic rotation in patients coma or low alertness intensive care unit (ICU) Semnan kowsar hospital

Public title

The effect of follow-up prevention or these of heel pressure ulcer, drop foot, and pelvic rotation in patients coma or low alertness intensive care unit (ICU) Semnan kowsar hospital

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients 20-70 years old Patients with Diabetic Heel Wounds Patients with heel soft tissue injuries

Exclusion criteria:

Patient dissatisfaction

Age

From **20 years** old to **70 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

Patients are allocated randomly with simple sequential allocation in one of the two study groups by help of sealed envelope and receive the intervention of the same group. The unit of randomization will be the referred patient. Sealed envelopes will be delivered to expert. With each patient's visit, one of the envelopes will be randomly selected by the patients and will be introduced as a study group. The stratification approach is not used.

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 Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2019-07-16, 1398/04/25

Ethics committee reference number

IR.SEMUMS.REC.1398.103

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

heel pressure ulcer

ICD-10 code

S91.0

ICD-10 code description

Open wound of ankle

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

Degree of hip rotation

Timepoint

Before and after the intervention

Method of measurement

Goniometer

2**Description**

Heel pressure ulcers

Timepoint

Before and after the intervention

Method of measurement

By software

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Only for comparison with intervention group, no treatment is performed.

Category

N/A

2**Description**

Intervention group: Heel pressure ulcer orthoses are used for patients (Unconscious or with low alertness) admitted to the intensive care unit of Kowsar Hospital in Semnan for 7 days.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Shahrukh Khojastehfar

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Amin Street , Semnan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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Semnan University of Medical Sciences, Basij Blvd,
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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

Shahrukh Khojastehfar

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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