

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

study of homecare's effects on prevention of the pressure ulcer in craniospinal injury patients

Protocol summary

Summary

Objective: Determine the impact of nursing home care on the prevention of pressure ulcers in patients with spinal lesions. Study design: randomized. Study population: All patients with craniospinal injury have been discharged from hospitals in Hamedan. Major inclusion criteria: Immediately after the discharge of patients with craniospinal injury, Patients should not have pressure ulcers, Predicting pressure ulcer patients based on the Borden scale with scores below 18 are, Patients must be aged between 40-75 years. Major exclusion criteria: Need for hospital readmission. Sample Size: 80 patients. Intervention: Implementation of the Protocol to prevent bedsores. Researcher, according to the schedule, to refer patients to home and care, including preparing and delivering designed training package, providing the means to prevent pressure ulcers and patient position change every 4-2 hours to perform. These impacts will be evaluated in both control and intervention. Primary outcomes: Reduce the risk of pressure ulcer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012070910217N1**

Registration date: **2012-10-02, 1391/07/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-02, 1391/07/11

Registrant information

Name

Mohammad vali Kian

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1264 4888

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research & technology, Hamadan university of medical sciences

Expected recruitment start date

2012-09-21, 1391/06/31

Expected recruitment end date

2013-03-15, 1391/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

study of homecare's effects on prevention of the pressure ulcer in craniospinal injury patients

Public title

Impact of nursing care on pressure ulcer prevention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Immediately after the discharge of patients with craniospinal injury; Patients should not have pressure ulcers; Predicting pressure ulcer patients based on the Borden scale with scores below 18 are; Patients must be aged between 40-75 years. Exclusion Criteria: Need for hospital readmission; Disaffiliate the patient and family; Having a history of diabetes; Having

advanced vascular disease serum albumin level less than 3/5 g/dL.

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Hamadan university of medical sciences

Street address

Hamadan university of medical sciences, Shahid Fahmideh st, Hamadan

City

Hamadan

Postal code

6517678835

Approval date

2012-08-12, 1391/05/22

Ethics committee reference number

1835/9/35/16/پ/د

Health conditions studied

1

Description of health condition studied

Evaluation the skin of pressure ulcers

ICD-10 code

L-89

ICD-10 code description

Decubitus ulcer and pressure area

Primary outcomes

1

Description

pressure ulcer

Timepoint

one month

Method of measurement

View and apply pressure ulcer scale

Secondary outcomes

1

Description

Severity of pressure ulcer

Timepoint

one month

Method of measurement

View and apply pressure ulcer scale

Intervention groups

1

Description

In the control group does not interfere and the patient's family will receive training from the hospital. these patients survey from incidence and degree of Bedsores every 72 hours

Category

Prevention

2

Description

In the intervention group, researcher go to patients home daily, and assess the health of the skin and pressure ulcer prevention protocol carries out. Protocols including skin care, use of support surfaces such as pillows and changing position every 2 hours. Floating mats are used in both.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

farshchian Hospital

Full name of responsible person

mohammad vali kian

Street address

Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research & technology, Hamadan university of medical sciences

Full name of responsible person

Ali Ghaleiha

Street address

Hamadan university of medical sciences, Shahid Fahmideh st, Hamadan

City

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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

Vice chancellor for research & technology, Hamadan university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Hamadan university of medical sciences

Full name of responsible person

mohammad vali kian

Position

Nurse

Other areas of specialty/work**Street address**

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty