# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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**

m.kian@umsha.ac.ir

**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**

Hamadan

**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**

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## Person responsible for scientific inquiries

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Msc in nursing

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## Person responsible for updating data

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**Position**

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**Other areas of specialty/work**

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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*