

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of sheep felt mattress on the prevention of pressure ulcers in patients admitted to the wards of Allameh Bohlool Gonabadi Hospital

Protocol summary

Study aim

The effect of sheep felt mattress on the prevention of pressure ulcers in patients

Design

A control trial with a control group, with a parallel, three-blind, randomized group, on 116 patients, will use permutation block randomization.

Settings and conduct

The study will be performed on patients admitted to the wards of Allameh Bohlool Gonabadi Hospital who are eligible to enter the study.

Participants/Inclusion and exclusion criteria

Entry requirements: Score of 13 or higher on the Braden scale
Informed consent of the patient or his / her guardian
No bed sores at the time of admission to the hospital
No uncontrolled diabetes
No entry conditions: Death of patient
Discharge before one week after the start of the study
Occurrence of any allergy to felt

Intervention groups

Intervention group: Before the intervention, the skin health of patients in the pressure areas will be examined and all mechanical, chemical and bacterial factors that cause pressure ulcers will be determined. In addition to changing the position every 2 hours, along with the wavy mattress, a felt mat (made by Devinfeltco) with cotton sheets will be used. The intervention lasts for at least a week and the sites prone to pressure ulcers will be examined daily by the Braden scale and the data will be recorded. Control group: Before the intervention, the skin health of patients in the pressure areas will be examined and all mechanical, chemical and bacterial factors that cause pressure ulcers will be determined. But patients will only receive routine care (changing position every 2 hours and a wavy mattress with a cotton cover).

Main outcome variables

bed sores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190622043968N3**

Registration date: **2022-05-11, 1401/02/21**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-11, 1401/02/21**

Update count: **0**

Registration date

2022-05-11, 1401/02/21

Registrant information

Name

Maryam Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5652 5792

Email address

moradi.mf69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-11, 1400/12/20

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sheep felt mattress on the prevention of pressure ulcers in patients admitted to the wards of Allameh Bohlool Gonabadi Hospital		Gonabad university of medical sciences, next to the Asian Road, Gonabad city, Razavi Khorasan, Iran	
Public title	The effect of sheep felt mattress on the prevention of pressure ulcers in patients	City	Gonabad
Purpose	Prevention	Province	Razavi Khorasan
Inclusion/Exclusion criteria		Postal code	9691793718
Inclusion criteria:	Score of 13 or higher on the Braden scale Informed consent of the patient or his / her guardian No bed sores at the time of admission to the hospital No uncontrolled diabetes	Approval date	2022-01-24, 1400/11/04
Exclusion criteria:	□ Death of the patient Discharge before one week after the start of the study Occurrence of any allergy to felt	Ethics committee reference number	IR.GMU.REC.1400.184
Age	No age limit	Health conditions studied	
Gender	Both	1	
Phase	N/A	Description of health condition studied	
Groups that have been masked	- Participant - Outcome assessor - Data analyser	Bed sore	
Sample size	Target sample size: 116	ICD-10 code	
Randomization (investigator's opinion)	Randomized	ICD-10 code description	
Randomization description	Samples will be selected using available sampling method and then assigned to the control and experimental groups by permutation block Randomization method	Primary outcomes	
Blinding (investigator's opinion)	Double blinded	1	
Blinding description	In this study, the evaluator, patient and analyst will be blinded and will not be aware of the type of intervention.	Description	
Placebo	Not used	Prevention of bed sore	
Assignment	Parallel	Timepoint	
Other design features		Before intervention and one week after intervention	
Secondary Ids	empty	Method of measurement	
Ethics committees		the Bets Jensen questionnaire	
1		Secondary outcomes	
Ethics committee		empty	
Name of ethics committee	Ethics Committee of Gonabad University of Medical Sciences	Intervention groups	
Street address		1	
		Description	
		Intervention group: Before the intervention, the skin health of patients in the pressure areas will be examined and all mechanical, chemical and bacterial factors that cause pressure ulcers will be determined. In addition to changing the position every 2 hours, along with the wavy mattress, a felt mat (made by Devinfeltco) with cotton sheets will be used. The intervention lasts for at least a week and the sites prone to pressure ulcers will be examined daily by the Braden scale and the data will be recorded.	
		Category	
		Prevention	
		2	
		Description	
		Control group: Before the intervention, the skin health of patients in the pressure areas will be examined and all mechanical, chemical and bacterial factors that cause pressure ulcers will be determined. But patients will only	

receive routine care (changing position every 2 hours and a wavy mattress with a cotton cover).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Behloul Gonabadi Hospital

Full name of responsible person

Maryam Moradi

Street address

Allameh Behoul Gonabadi Hospital; Parstar blvd;
Saadi street, Gonabad city, Razavi Khorasan, Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691797852

Phone

+98 51 5723 6832

Email

moradi.mf69@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Shahla Khosravan

Street address

Research Center for Social Determinants of Health,
Gonabad University of Medical Sciences, Gonabad
university of medical sciences, next to the Asian Road,
Gonabad city, Razavi Khorasan, Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 9025

Email

moradi.mf69@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Maryam Moradi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Geriatrics

Street address

Gonabad university of medical sciences, next to the
Asian Road, Gonabad city, Razavi Khorasan, Iran

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Phone

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable