

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparing the effects of Gum gel pads with foam to prevent bedsores in trauma patients admitted to the intensive care unit

Protocol summary

Summary

Comparison Gum gel and foam cushions to prevent bedsores Study: randomized double blind (The patients and researchers) Study population: patients with trauma admitted to ICU Inclusion criteria: the age over 15 and under 65 years; Patients without underlying disease (diabetes, skin diseases) and who are admitted to trauma ward ; The risk of bed sores was under 18 according to the Braden Scale score; the minimum duration of stay in the ICU was 5 days. exclusion criteria: the patient died; allergic reactions; appearance of skin redness (onset of bedsores) in study area; Lack of consent or opt-out patients or their families to continue cooperation Interventions: Intervention group (Gum gel pad): control group (Foam pad) Intervention time: from 2016-03-20 until 2016-03-19 The primary outcome: the prevention of pressure ulcers in both groups Secondary outcome: the incidence of pressure ulcers in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091129781N1**

Registration date: **2016-11-22, 1395/09/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-22, 1395/09/02

Registrant information

Name

Javad Shakibamehr

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3542 3970

Email address

shakibamj2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sabzevar University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Gum gel pads with foam to prevent bedsores in trauma patients admitted to the intensive care unit

Public title

Comparison Gum gel and foam cushions to prevent bedsores

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the age over 15 and under 65 years; Patients without underlying disease (diabetes, skin diseases) and who are admitted to trauma ward ; The risk of bed sores was under 18 according to the Braden Scale score; the minimum duration of stay in the ICU was 5 days. exclusion criteria: the patient died; allergic reactions; appearance of skin redness (onset of

bedsores) in study area; Lack of consent or opt-out patients or their families to continue cooperation

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Sabzevar, Khorasan Razavi

City

Sabzevar

Postal code

Approval date

2016-05-17, 1395/02/28

Ethics committee reference number

IR.medsab.rec.95.14

Health conditions studied

1

Description of health condition studied

Trauma patients admitted to the intensive care unit

ICD-10 code

L89.0

ICD-10 code description

Stage I decubitus ulcer and pressure area

Primary outcomes

1

Description

The prevention of pressure ulcers in both groups

Timepoint

Since the beginning of the study to 10 days

Method of measurement

check list

Secondary outcomes

1

Description

The incidence of pressure ulcers in both groups.

Timepoint

Since the beginning of the study to 10 days

Method of measurement

check list

Intervention groups

1

Description

The control group consisted of patients for whom the foam padding is used

Category

Prevention

2

Description

The intervention group consisted of patients for whom the Gum gel pad is used

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Javad shakibamehr (Head nurse)

Street address

Taleghani Hospital, Ferdowsi intersection, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Sabzevar University of Medical Sciences

Full name of responsible person

Mr. Malvndy

Street address

School of Nursing, Sabzevar University of Medical Sciences, Sabzevar

City

Sabzevar

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, Sabzevar 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**

Sabzevar University of Medical Sciences

Full name of responsible person

Javad Shakibamehr

Position

MSC Critical Care Nursing

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

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Mashhad University of Medical Sciences

Full name of responsible person

Masud Mozafar Jalali

Position

Nursing

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

Vakil Abad, Mashhad

City

Mashhad

Postal code**Phone**

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Fax**Email****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