Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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Person responsible for updating data

Contact
Name of organization / entity
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
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00
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