Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Evaluation of the Effectiveness of Preventive Nursing care Based on Braden Predictive Scale on the Incidence of Pressure Ulcers in Patients Admitted to the Intensive care Unit

Protocol summary

Study aim
Determining the effectiveness of Broaden scale-based preventive care in the development of pressure ulcers

Design
Clinical trial with control group, with parallel randomized groups on 72 patients, SPSS software was used for randomization.

Settings and conduct
In the intervention group, the checklist of nursing measures for preventing pressure ulcers is based on six subscales of Braden (mobility, activity, skin moisture, nutrition and sensory and abrasion perception scales). The researchers will train the nurses, then the researcher and the researcher's assistant. They will be present in all shifts on a daily basis and assist the treatment staff during the intervention and nursing care. Then a checklist is recorded in each shift by the researcher after the intervention group. Also, the Braden scale score is scored four times by the researcher, at the beginning of the study and the first 48 hours The second 48 hours and the third 48 hours are completed and recorded for patients. After 6 days, the researcher examines the incidence of pressure ulcers in terms of the degree of pressure ulcers based on the instrumentation using three criteria: wound size, amount of wound secretions and type of tissue formed

Participants/Inclusion and exclusion criteria
The patient is hospitalized in the intensive care unit and is not less than 18 years old and does not have skin disease.

Intervention groups
ntervention group: Performing interventions in Braden subscale (six cutting subscales including sensory perception, skin moisture, activity, mobility, nutrition and wear) and completing Braden checklist in 48 hours 1, second 48 hours, third 48 hours Control group: In the control group, routine and routine care is based on the usual schedule.

Main outcome variables
Bedsore

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200822048476N1**
Registration date: **2020-10-24, 1399/08/03**
Registration timing: **retrospective**

Last update: **2020-10-24, 1399/08/03**
Update count: **0**

Registration date
2020-10-24, 1399/08/03

Registrant information

Name
Khadejeh Khodayari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3373 8538

Email address
kh.khodayari@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-04, 1398/07/12

Expected recruitment end date
2021-03-11, 1399/12/21

Actual recruitment start date
2020-04-21, 1399/02/02

Actual recruitment end date
2020-07-01, 1399/04/11
Trial completion date
2020-08-16, 1399/05/26

Scientific title
Evaluation of the Effectiveness of Preventive Nursing care Based on Braden Predictive Scale on the Incidence of Pressure Ulcers in Patients Admitted to the Intensive care Unit

Public title
Prevention of bed sores in the intensive care unit
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 Years BeingHospitalized in the Intensive Care Unit Complete Immobility Due to Various Therapeutic Causes Lack of Evidence of Bed Sores At the Beginning of Hospitalization In the Ward No Underlying Skinn D iseases Earn a Score of 14 or Less on the Braden Scale No infection Underlying Diseases: Diabetes, Cerebrovascular Disorders, Cardiopulmonary Failure, Peripheral Vascular Disease and Peripheral Edema
Exclusion criteria:
Smoking during the last month
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
More than 1 sample in each individual
Number of samples in each individual: **36**
Being Hospitalized in the ICU Intensive Care Unit
Actual sample size reached: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
First, the final sample size, which is 72 people, using winpepi11/0 software with block randomization method, 12 blocks of 6 are assigned to the control and test groups, so that in each of the 6 blocks, 3 people are assigned to the test group. And 3 people are assigned to the control group. This software creates random control and test groups. The sampling method of the test and control groups in these blocks is random. Steps to use the software: Etcetera - select the randomallocation option and then select randomized bahnced and finally successive blocks
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahwaz University of Medical Sciences
Street address
no.4 west golestan,asfand town Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
15794- 61357
Approval date
2019-05-18, 1398/02/28
Ethics committee reference number
IR.AJUMS.REC.1398.160

Health conditions studied

1

Description of health condition studied
Bedsore of patients admitted to the intensive care unit
ICD-10 code
L89
ICD-10 code description
Pressure ulcer

Primary outcomes

1

Description
Bedsore
Timepoint
The first 48 hours, the second 48 hours and the third 48 hours
Method of measurement
Braden scale-posh scaling

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, bed sore prevention is based on the Braden scale checklist, which includes subscales (mobility, activity, skin moisture, nutrition, sensory

perception). And assist staff during nursing interventions and care. The Braden scale was recorded by the researcher at the beginning of the study, the first 48 hours, the second 48 hours and the third 48 hours. Care and prevention measures include: Nursing interventions in the mobility subscale: 1. Adjusting the patient position change program based on the hourly chart of the patient's position was changed to the designated position every three hours.2. Change position regularly at least every 2 hours 3. Further change position If the inflamed and reddened area does not change color (does not fade) with finger pressure Nursing interventions in the subscale of activity: 1. Helping the patient to maintain activity as much as possible 2. Inactive exercises were performed, especially in the legs. Exercises were performed in the range of motion. Nursing interventions in the skin moisture subscale: 1. Keep the skin clean and dry at all hours 2. Clean and dry the skin after each disposal 3. Use of a thin layer of oxide oxide to protect the patient's skin involuntarily, after washing and drying the perineum, groin and batex area. Provide adequate nutrition and fluids 2. Provide a diet high in protein, protein and minerals 3. Consult a nutritionist to assess nutritional status in a timely manner 4. Control of serum albumin g / dl 5-5-5 Nursing interventions in the subscale of sensory perception: 1. Evaluation of anesthesia in all areas of the body 2. Complete care of areas without sensation- Nursing interventions in the wear subscale: 1. Reducing the level of pressure: Pillow will be used to reduce the pressure in bone ridges

Category

Prevention

2

Description

Control groupIn the control group, nursing care will be performed by the nurse to prevent the occurrence of pressure ulcers. However, no intervention will be performed by the researcher in the control group and only a part of unplanned nursing care is done in the form of a checklist of nursing interventions for the intervention group. For the control group, routine care is performed, which includes: changing the patient 2 hours 2- Keeping the patient's skin clean and dry 3- Using a wavy mattress 4- Examining and direct observation of the nurse in each shift from areas prone to pressure ulcers 5- Feeding patients using ordinary interamyl gavage powder 6- Using a sponge and lukewarm water for the patient's bath. Also for the control group, the researcher will complete and record the Braden scale 4 times, including the beginning of the study and the first 48 hours, the second 48 hours, the third 48 hours for patients

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive care unit of Golestan and Imam Ahvaz hospitals

Full name of responsible person

Khadegeh khodayari

Street address

no.4 west golestan.asfand Blvd,golsetan Ahvaz

City

ahvaz

Province

Khouzestan

Postal code

15794- 61357

Phone

+98 61 3373 8283

Email

Kh.khodayari@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Marzieh Asadi Zakir

Street address

Iran, Khuzestan province, Ahvaz, Medical Sciences Boulevard, Golestan, Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8283

Email

marziyehasadizakerm@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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
Ahvaz University of Medical Sciences

Full name of responsible person
Marzieh Asadi Zakir

Position
Dean of Ahwaz School of Nursing and Midwifery

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Iran, Khuzestan province, Ahvaz, Medical Sciences Boulevard, Golestan, Jundishapur University of Medical Sciences

City
ahvaz

Province
Khouzestan

Postal code
6373174715

Phone
+98 71 4224 9

Email
marziyehasadizakerm@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Marzieh Asadi Zakir

Position
Head of Ahwaz School of Nursing and Midwifery

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Iran, Khuzestan province, Ahvaz, Medical Sciences Boulevard, Golestan, Jundishapur University of Medical Sciences

City
ahvaz

Province
Khouzestan

Postal code
6373174715

Phone
+98 61 3373 8283

Email
marziyehasadizakerm@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Marzieh Asadi Zakir

Position
Consultant, Professor, Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Iran, Khuzestan province, Ahvaz, Medical Sciences Boulevard, Golestan, Jundishapur University of Medical Sciences

City
ahvaz

Province
Khouzestan

Postal code
6373174715

Phone
+98 61 3373 8283

Email
marziyehasadizakerm@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified individuals

When the data will become available and for how long
Access period starts from 1400

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
Using the data to carry out other projects in the field of preventive and curative care

From where data/document is obtainable
1- marjannaseri33@gmail.com 2- 09385828712 number

What processes are involved for a request to access data/document
Earn a request

Comments