

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Braden 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

Intervention 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)

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+98 61 3373 8538

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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 Being Hospitalized 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

AgeFrom **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

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no.4 west golestan,asfand town Ahvaz

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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 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 group In 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Marzieh Asadi Zakir

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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 Ahvaz School of Nursing and Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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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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