Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between effect of Zinc Oxide and Vaseline in prevention pressure ulcer in patients

Protocol summary

Study aim

Comparison of the preventive effect of zinc oxide and vaseline on pressure injury in patients hospitalized in the special care department of Shahid Rajaei Hospital, Qazvin.

Design

A clinical trial of 4 intervention groups and one control group was randomized on 20 patients in each group and a total of 100 patients using ball and bag sampling methods.

Settings and conduct

Group 1 and 2 patients, for 10 days and twice a day, the skin of the patients will be examined and all pressure points of the body will be covered with zinc oxide twice a day in the morning and at night. In group 1, zinc oxide will be used directly on the skin of patients, and in group 2, gas impregnated with zinc will be used on the skin of patients. Patients in groups 3 and 4, for 10 days and twice a day, the skin of the patients will be examined and all pressure points will be covered with Vaseline.

Participants/Inclusion and exclusion criteria

1- Informed consent of the patient or the patient's family to participate in the research. 2- Patients with medium and high risk based on the score obtained from Braden's criteria upon entering the department. 3- Age (18-70) years (because Braden's criterion is specific to the age above 18). 4- Absence of underlying disease (diabetes, skin diseases, vascular diseases) Non-entry conditions Suffering from a pressure injury at the time of entering the ward 2- Circumstances in which a change in the patient's condition is indicated. 3- Age less than 18 years or more than 70 years 4- Having diabetes and various skin and vascular diseases

Intervention groups

Four groups: 1- Zinc oxide with dressing, 2- Vaseline with dressing, 3- Zinc oxide without dressing, 4- Vaseline without dressing and the control group.

Main outcome variables

- type of ventilation in the ward - the first measured albumin level - the first measured hemoglobin level - pressure injury - location of the wound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230711058739N1**
Registration date: **2023-07-19, 1402/04/28**
Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**
Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Fateme Safari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison between effect of Zinc Oxide and Vaseline in prevention pressure ulcer in patients

Public title
The effect of zinc oxide and vaseline in preventing pressure ulcer

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent of the patient or the patient's family to participate in the research Patients with medium and high risk based on the score they get from Braden's criteria upon entering the department. Age (18-70) years (because Braden's criterion is for people over 18). Absence of underlying disease (diabetes, skin diseases, vascular diseases)
Exclusion criteria:
Suffering from a pressure injury at the time of entering the ward 2- Circumstances in which a change in the patient's condition is indicated. 3- Age less than 18 years or more than 70 years 4- Having diabetes and various skin and vascular diseases

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients who meet the criteria for inclusion in the study were selected by random sampling method and divided into four groups: 1- Zinc oxide with dressing, 2- Vaseline with dressing, 3- Zinc oxide without dressing, 4- Vaseline without dressing and the control group. will be placed. The selection of the ball from the bag will be done by one of the ward nurses who is not aware of the study. Due to the fact that in the present study, an attempt has been made to prevent the occurrence of pressure injuries in all vulnerable points, therefore, the use of zinc oxide and Vaseline will support all pressure points of the body. Since according to studies, the average duration of pressure injury in patients hospitalized in the intensive care unit is the first 10 days, in group 1 and 2 patients, the skin of the patients was examined twice a day for 10 days and using Zing. Oxide will cover all pressure points of the body twice a day in the morning and at night with this medicine. The amount of medicine used varies according to the fitness of the patient, and it is important that all pressure points are well covered with this medicine. In group 1, zinc oxide will be used directly on the skin of patients, and in group 2, gas impregnated with zinc will be used on the skin of patients. Patients in groups 3 and 4, for 10 days and twice a day, the skin of the patients will be examined and all pressure points will be covered with Vaseline. In group 3, Vaseline will be used directly on the skin of patients, and in group 4, gauze impregnated with Vaseline will be used on the skin of patients. The amount of medicine used in this group will also be different according to the size of the patient, and the important thing is that all pressure points are covered with medicine. Treatment centers will be conducted and there will be no intervention in routine nursing care. The skin of the patients was examined by the research team twice within 24 hours and each time when the condition of the patients changed in terms of occurrence of pressure injuries using standard tools and in case of ulcers, the degree, size, location and other cases were recorded in the special file for each patient. The present study will be designed and registered. The members of the research team will carry out the relevant interventions on the patients' beds in order to maintain ethical issues according to the purpose of the research.

Blinding (investigator's opinion)
Not 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 Qazvin University of Medical Sciences
Street address
Qazvin, Kausar town, South Miyad St., 7 Shahamat alley, No. 5, 2nd floor
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Province
Qazvin
Postal code
3471646118

Approval date
2023-06-28, 1402/04/07

Ethics committee reference number
IR.QUMS.REC.1402.033

Health conditions studied

1

Description of health condition studied
Bedsores in the intensive care unit

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Prevention of bedsores
Timepoint
Before reading - every time you change position - twice in 24 hours in 10 days
Method of measurement
Braden tool - pressure injury grading tool - checklist of demographic variables

Secondary outcomes

1

Description
The effect of zinc oxide and vaseline
Timepoint
2 times within 24 hours and within 10 days
Method of measurement
Compressive damage grading tool - Braden tool

Intervention groups

1

Description
Intervention group: zinc oxide receptor group without dressing
Category
Treatment - Devices

2

Description
Intervention group: Vaseline receiving group without dressing
Category
Treatment - Devices

3

Description
Intervention group: Zinc oxide with dressing
Category
Treatment - Devices

4

Description
Intervention group: Vaseline with dressing
Category
Treatment - Devices

5

Description
Control group: Not using zinc and vaseline and doing routine care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Special care department of Shahid Rajaei Hospital, Qazvin
Full name of responsible person
Farnoosh Rashvand
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No. 5, Haft Shehamat Alley, Kausar, Qazvin
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Sponsors / Funding sources

1

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