

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 28 3377 8507

##### Email address

fatemesafari75@gmail.com

##### 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 Zinc 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

**City**

Qazvin

**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**

Bedsore 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

**Street address**

No. 5, Haft Shehamat Alley, Kausar, Qazvin

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3471646118

**Phone**

+98 938 672 8516

**Email**

fatemesafarii75@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

farnoosh rashvand

**Street address**

No. 5, Haft Shehamat Alley, Kausar, Qazvin

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3471646118

**Phone**

+98 938 672 8516

**Email**

fatemesafarii75@gmail.com

**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****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Fatima Safari Al-Muti

**Position**

nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 5, Haft Shehamat Alley, Kausar, Qazvin

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3471646118

**Phone**

+98 28 3377 8507

**Email**

fatemesafarii75@gmail.com

3471646118

**Phone**

+98 28 3377 8507

**Email**

n.rashvand@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Fatima Safari Al-Muti

**Position**

nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

2nd floor, No. 5, No. 7, Shahamat alley, South Miyad St., Qazvin, Kausar town

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3471646118

**Phone**

+98 28 3377 8507

**Email**

fatemesafarii75@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

farnoosh rashvand

**Position**

Associate Professor, Faculty of Nursing, Qazvin University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Qazvin - Qazvin University of Medical Sciences, Faculty of Nursing and Midwifery

**City**

Qazvin

**Province**

Qazvin

**Postal code****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