Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative study of the effect of hydrocolloid dressing and alpha ointment on pressure ulcer healing in elderly patients hospitalized in intensive care units

Protocol summary

Study aim
Comparative study of the effect of hydrocolloid dressing and alpha ointment on pressure ulcer healing in elderly patients hospitalized in intensive care units

Design
This study is a one-blind clinical trial. The study population will be all patients referred to Shohada hospital of Kermanshah. 126 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct
The study, which will be conducted at Shohada hospital of Kermanshah, is one-blind one, that the data analyzer will kept blind to the allocation of study groups. Prior to any intervention, the wound characteristics will be recorded in a checklist based on the Pressure Ulcer Scale (PUSH).

Participants/Inclusion and exclusion criteria
Inclusion criteria: More than 60 years old; Patients with pressure ulcers Exclusion criteria: People with diabetes

Intervention groups
The first intervention group will receive an alpha ointment daily for 5 weeks after thoroughly rinsing the wound with normal saline and drying it with sterile gas. The second intervention group will receive hydrocolloids every 48 to 72 hour for 5 weeks, after rinsing the wound with normal saline and drying it with sterile gas

Main outcome variables
Wound healing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N144**
Registration date: **2020-03-29, 1399/01/10**
Registration timing: **prospective**

Last update: **2020-03-29, 1399/01/10**
Update count: **0**

Registration date
2020-03-29, 1399/01/10

Registrant information

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Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-08, 1399/01/20

Expected recruitment end date
2020-06-04, 1399/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of hydrocolloid dressing and alpha ointment on pressure ulcer healing in elderly patients hospitalized in intensive care units

Public title

Comparative study of the effect of hydrocolloid dressing and alpha ointment on pressure ulcer healing in elderly patients hospitalized in intensive care units

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
More than 60 years old Patients with pressure ulcers

Exclusion criteria:
People with diabetes

Age
From **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the random number table, patients are divided into two groups of 63. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the first intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the second intervention group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyzer was kept blind to the allocation of study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2020-02-04, 1398/11/15

Ethics committee reference number
ir.kums.rec.1398.1146

Health conditions studied

1

Description of health condition studied
pressure ulcer

ICD-10 code
L89

ICD-10 code description
Pressure ulcer

Primary outcomes

1

Description
Wound healing

Timepoint
Baseline, once a week for 5 weeks

Method of measurement
Based on observation

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group will receive an alpha ointment daily for 5 weeks after thoroughly rinsing the wound with normal saline and drying it with sterile gas

Category
Treatment - Other

2

Description
The second intervention group will receive hydrocolloids every 48 to 72 hour for 5 weeks, after rinsing the wound with normal saline and drying it with sterile gas

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada Hospital

Full name of responsible person
Samin Sharifi
Street address
Shohada Hospital, Shahid Beheshti Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
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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
Kermanshah 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Informed Consent Form
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The main outcomes of the study will be shared.
When the data will become available and for how long
3 months
To whom data/document is available
If requested, results will be made available to other academic researchers
Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else
From where data/document is obtainable
Send E-mail to the responsible for the update to get the documentation
What processes are involved for a request to access data/document
Documentation will be emailed within a 15-day timeframe
Comments