

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 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

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

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

City

Kermanshah

Province

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6714663156

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+98 83 3835 4115

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

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

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fnajafi@kums.ac.ir

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**

Kermanshah University of Medical Sciences

Full name of responsible person

Samin Sharifi

Position

MSc in Elderly Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Faculty of Nursing and Midwifery, Dolatabad Blvd, Isar Square

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Parvin Abbasi

Position

Member of Kermanshah University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nursing Education

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

Kermanshah University of Medical Sciences

Full name of responsible person

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Latest degree

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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

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