Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of topical formulation of whey protein on the prevention of pressure ulcer in patients admitted to the intensive care unit

Protocol summary

Study aim
Evaluation of the effect of topical formulation of whey protein on the prevention of pressure ulcer in patients admitted to the intensive care unit

Design
Randomized, double blinded, controlled, clinical trial with a parallel group was designed among 80 patients (40 patients in each group) . Card shuffling was used for randomization.

Settings and conduct
This randomized, clinical trial was designed to evaluate the effect of topical formulation of whey protein on prevention of pressure ulcer. For this evaluation, topical cream of whey protein 10% with eucerin as the base, was applied in the sacrum area of critically ill patients admitted to ICU, twice daily for 7 days, and compared its effect with eucerin cream as a placebo. Patients were followed daily for pressure ulcer based on PUSH criteria. This is a double blinded study, that means participants, and the assessors of the outcomes are unaware of the study group, and moreover seemingly identical topical formulations were used in intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adult patients without pressure ulcer on the intensive care unit (ICU) admission Patients with systolic blood pressure equal or more than 100 millimetre of mercury Exclusion criteria: Patients with prior hospitalization in other wards of the hospital before admission in the ICU Patients with more than 24 hours from ICU admission Patients with diabetes mellitus

Intervention groups
Intervention group: Topical cream of whey protein 10% with eucerin as the base, was made and applied on the sacrum, twice daily, for 7 days. Control group: Topical placebo cream containing eucerin (without whey protein) was applied on the sacrum, twice daily, for 7 days.

Main outcome variables
Pressure ulcer PUSH score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150221021159N2**
Registration date: **2020-06-17, 1399/03/28**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-17, 1399/03/28**
Update count: **0**

Registration date
2020-06-17, 1399/03/28

Registrant information

Name
Shadi Farsaei

Name of organization / entity
Isfahan 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
2019-09-25, 1398/07/03

Expected recruitment end date
2020-12-23, 1399/10/03

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of topical formulation of whey protein on the prevention of pressure ulcer in patients admitted to the intensive care unit

Public title
Evaluation of the effect of topical whey protein on the prevention of pressure ulcer
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients without pressure ulcer on the intensive care unit (ICU) admission Patients with systolic blood pressure equal or more than 100 millimetre of mercury
Exclusion criteria:
Patients with prior hospitalization in other wards of the hospital before admission in the ICU Patients with more than 24 hours from ICU admission Patients with diabetes mellitus
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Numbers from 1 to 80 were written on the separated cards, and 40 cards were assigned to each group of protein whey and placebo. These cards were placed in the box, and one card was selected randomly from these shuffled cards for each eligible patient, on the study recruitment day. Specific topical cream was applied for each patient based on the number of selected card. It should be mentioned that participants, health care providers, assessor and data collector were not aware of treatment assignment.
Blinding (investigator's opinion)
Double blinded
Blinding description
Seemingly identical topical formulations were used in control and whey protein group. Moreover, participants, health care providers, assessor and data collector unaware of allocated code in each study group.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical sciences
Street address
Bldg No. 4, Isfahan University of Medical Sciences and Health Services, Hizar jarib street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-07-09, 1398/04/18
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.216

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
Scale of pressure ulcer using the Pressure Ulcer Scale for Healing (PUSH) tool
Timepoint
From the onset of study, daily, for 7 days.
Method of measurement
The Pressure Ulcer Scale for Healing (PUSH) tool

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Topical cream of whey protein 10% with eucerin as the base, was made and applied on the

sacrum, twice daily, for 7 days.

Category

Prevention

2

Description

Control group: Topical placebo cream containing eucerin (without whey protein) was applied on the sacrum, twice daily, for 7 days.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

AlZahra hospital

Full name of responsible person

Shadi Farsaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Shadi Farsaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Position

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Person responsible for updating data

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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