

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 2618

##### Email address

farsaei@pharm.mui.ac.ir

##### 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**

Isfahan

**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

**Street address**

No.53, 29th Alley , Chahar Bagh Paeen Ave., Isfahn, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8148614481

**Phone**

+98 31 3792 7071

**Email**

sh.farsaei@gmail.com

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh haghjou Javanmard

**Street address**

Vice chancellery research and technology, Bldg No. 4, Isfahan University of Medical Sciences and Health Services, Hizarjarib st.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 8138

**Email**

research@mui.ac.ir

**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

**Street address**

Clinical pharmacy and pharmaceutical practices department, Pharmacy faculty, Isfahan university of medical sciences, Hezarjerib St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 7071

**Email**

Farsaei@pharm.mui.ac.ir

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

Esfahan University of Medical Sciences

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Shadi Farsaei

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Associate professor

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Medical Pharmacy

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**Email**  
Farsaei@pharm.mui.ac.ir

## Person responsible for updating data

### 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  
**Street address**  
Clinical pharmacy and pharmaceutical practices  
department, Pharmacy faculty, Isfahan university of  
medical sciences, Hezarjerib St.  
**City**  
Isfahan  
**Province**

Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3792 7071  
**Email**  
Farsaei@pharm.mui.ac.ir

## 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