

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of the effect of crystalline insulin and topical oxygen on pressure ulcer healing in patients admitted to intensive care units, a single-blind clinical trial

#### Protocol summary

##### Study aim

Determining and comparing the effect of crystalline insulin and topical oxygen in the healing of pressure ulcers in patients admitted to the intensive care units of Kashani Hospital in Shahrekord

##### Design

Clinical trial, Parallel, one-way blind, on 60 patients

##### Settings and conduct

3rd degree bed sores, hospitalized in the intensive care unit of Kashani Hospital in Shahrekord. There are three groups of topical insulin and topical and control oxygen. Face twice daily for two weeks, in the group with topical oxygen therapy in addition to routine treatment twice daily topical oxygen for 20 minutes and twice a day for 2 weeks and in the control group routine treatments including daily washing with normal saline. The wounds are then followed for two weeks.

##### Participants/Inclusion and exclusion criteria

1. Patients aged 19-65 years who have grade 3 pressure ulcer due to severe concussion (<GCS <8).
2. Do not suffer from organ failure
3. No diabetes, burns, chronic skin disease, diarrhea, vascular problems and hypoalbuminemia
4. No history of smoking, drug or alcohol addiction
5. Absence of infectious symptoms in the wound (swelling, redness around the wound and foul-smelling and purulent discharge)
6. Absence of cachexia symptoms (folds on the back of the arm, the patient's appearance, protrusion of the zygomatic arch and emptying of the temporal cavity)
7. Not taking systemic corticosteroids during the last year
8. The legal guardian of the patient has agreed to participate in the study and has signed the consent form.

##### Intervention groups

Three groups of recipient intervention: 1- Topical insulin: Insulin recipient with normal saline wash 2- Topical oxygen: Topical oxygen with normal saline wash 3- Control: Normal saline wash only

#### Main outcome variables

Wound degree Wound area The amount of discharge

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210508051228N2**

Registration date: **2021-08-16, 1400/05/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-08-16, 1400/05/25**

Update count: **0**

##### Registration date

2021-08-16, 1400/05/25

##### Registrant information

##### Name

Ali Hasanpourdehkordi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3333 0064

##### Email address

a.dehkordi1398@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-28, 1399/12/10

##### Expected recruitment end date

2021-08-23, 1400/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of crystalline insulin and topical oxygen on pressure ulcer healing in patients admitted to intensive care units, a single-blind clinical trial

**Public title**  
Comparison of the effect of crystalline insulin and topical oxygen on pressure ulcer healing

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

3rd degree bed sores

**Exclusion criteria:**

Wounds with other causes Unfavorable physical condition

**Age**

From **19 years** old to **65 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The statistical consultant did not know the type of interventions and the names of the groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Shahrekord University of Medical Sciences

**Street address**

kashani

**City**

shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8813833435

**Approval date**

2021-02-23, 1399/12/05

**Ethics committee reference number**

IR.SKUMS.REC.1399.263

**Health conditions studied**

1

**Description of health condition studied**

bedsore

**ICD-10 code**

L99

**ICD-10 code description**

Other disorders of skin and subcutaneous tissue in diseases classified elsewhere

**Primary outcomes**

1

**Description**

Bed wound healing rate

**Timepoint**

Before and after the effect of insulin and topical oxygen

**Method of measurement**

Graduated spatula

**Secondary outcomes**

1

**Description**

Wound discharge

**Timepoint**

After the intervention

**Method of measurement**

Consumable sterile gas

**Intervention groups**

1

**Description**

Intervention group 1: Topical crystal insulin treatment twice a day for two weeks for every 10 cm<sup>2</sup> of wound 4 units of regular insulin dissolved in one cc of normal saline and sprayed on the wound with an insulin syringe. Covered with camouflage.

**Category**

Treatment - Drugs

2

**Description**

"Intervention group 2": In addition to routine treatment with topical oxygen, they will receive twice daily topical oxygen at a rate of 10 liters per minute for 20 minutes

and twice a day for 2 weeks.

**Category**

Treatment - Drugs

**3**

**Description**

"Control group": Routine treatments include daily washing with normal saline and then the wound is covered with a conventional dressing (camphile) and followed for two weeks.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Kashani Hospital

**Full name of responsible person**

Ismail Tahmasebi

**Street address**

Varzesh

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8813833435

**Phone**

+98 38 3322 9266

**Email**

miladghaderi4343@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Masoumeh Moezzi

**Street address**

Kashani

**City**

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**Phone**

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**Email**

mmoezzi@skums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahre-kord University of Medical Sciences

**Proportion provided by this source**

80

**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**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Lotfollah Afzali

**Position**

Research Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Plastic and Cosmetic Surgeon

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Kashani

**City**

Shahrekord

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**Email**

Dr.afzali.sl@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Ali Hassanpourdehkordi

**Position**

Research Consultant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Farrokh Yadalahi Farsani

**Position**

Research Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

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**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8813833435

**Phone**

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**Email**

miladghaderi4343@gmail.com

**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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

In the full text of the thesis

**When the data will become available and for how long**

After the explanation of the thesis

**To whom data/document is available**

Researchers and students of the centers

**Under which criteria data/document could be used**

Referral of research work references

**From where data/document is obtainable**

University Library

**What processes are involved for a request to access data/document**

Submit request and review

**Comments**