Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+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 cm2 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

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Chahar-Mahal-va-Bakhtiari

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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

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

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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
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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
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