

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of Topical Oxygen on Wound healing of trauma patients admitted in Intensive Care Units of Kerman University of Medical Sciences

Protocol summary

Summary

Aim: The incidence of pressure sore in critically ill patients is high and this can be increased the risk of mortality. So this study designed to evaluation of the effect of topical oxygen therapy on pressure sore healing of traumatic critically ill patients. Design: A double blind clinical trial study on 80 eligible patients (inclusion criteria: 17-65 Y/O, without underlying medical conditions including organ failure, diabetes and burns. Exclusion criteria: systemic corticosteroid usage, chronic skin disease organ failure) will be done after assigned to two groups. Intervention: In the intervention group, the wound surface is in contact with moist oxygen at a rate of 10 liters per minute for 20 minutes, every day and then covered with a sterile gauze dressing. In the control group The routine dressing will be done. The intervening period will be 15 days. Outcomes: The area of pressure ulcer (length, width and depth) with Push scale and the stage of wound by direct observation are determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602275426N9**

Registration date: **2016-08-12, 1395/05/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-12, 1395/05/22

Registrant information

Name

Mehdi Ahmadinejad

Name of organization / entity

Anesthesiology department, Kerman University of

Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kerman University of Medical Sciences

Expected recruitment start date

2016-05-17, 1395/02/28

Expected recruitment end date

2016-11-18, 1395/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Topical Oxygen on Wound healing of trauma patients admitted in Intensive Care Units of Kerman University of Medical Sciences

Public title

Effect of Topical Oxygen on healing of Pressure ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 17-65 Y/O; without underlying medical conditions including organ failure, diabetes and burns.

Exclusion criteria: systemic corticosteroid usage; chronic skin disease; organ failure; patient death

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kerman University of Medical Sciences

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jihad Blvd, Somayye Crossroads, Shariaati St, Kerman

City

Kerman

Postal code

7619813159

Approval date

2016-05-17, 1395/02/28

Ethics committee reference number

IR.KMU.REC.1395.18

Health conditions studied**1****Description of health condition studied**

Pressure ulcers

ICD-10 code

L89

ICD-10 code description

Decubitus ulcer and pressure area

Primary outcomes**1****Description**

Stage of Pressure ulcer

Timepoint

Every three day

Method of measurement

Direct observation of wound

2**Description**

The area of pressure ulcer (length, width and depth)

Timepoint

Every three day

Method of measurement

Push Scale

Secondary outcomes

empty

Intervention groups**1****Description**

In the intervention group, the wound surface is in contact with moist oxygen at a rate of 10 liters per minute for 20 minutes, every day and then covered with a sterile gauze dressing.

Category

Treatment - Other

2**Description**

In the control group only used routine dressing.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Bahonar Hospital

Full name of responsible person

Mehdi Ahmadinejad

Street address

Shahid Bahonar Hospital, Qarani St, Valiasr Crossroads, Shariaati St, Kerman

City

Kerman

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

Vice chancellor for research of Kerman University of Medical Sciences

Full name of responsible person

Dr Pardakhti

Street address

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City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Ahmadinejad

Position

Assistant Professor- Fellow of Intensive Care

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty