

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of topical high pressure oxygen therapy on healing of bed sore

Protocol summary

Summary

The objective of present study was to determine the effects of "Topical High Pressure Oxygen Therapy" on healing of bed sore. Through a randomized single-blinded clinical trial, 100 patients were randomly allocated into 2 equal groups. Inclusion criteria were presence of bed sore, degree 1-4 based on classification of world bed sore category, and exclusion criteria was presence of vascular damage such as "Burger Syndrome". For intervention group in addition to routine wound care, topical high pressure oxygen (10 L/m) with catheter was applied for 20 minutes, 3 times a day but for control group just routine wound care was done. Primary outcome was size of bed sore, measured before intervention and every 48 hours in both groups for 4 week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138708051407N1**

Registration date: **2009-04-25, 1388/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-04-25, 1388/02/05

Registrant information

Name

Jalil Azimian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 1223 7267

Email address

jazzimian@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2006-03-11, 1384/12/20

Expected recruitment end date

2008-03-10, 1386/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of topical high pressure oxygen therapy on healing of bed sore

Public title

Topical oxygen therapy on healing of bed sore

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of bed sore degree 1-4 based on classification of world bed sore category, signing written informed consent Exclusion criteria: Presence of vascular damage such as "Burger Syndrome"

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences

City

Qazvin

Postal code

3414638588

Approval date

2006-01-10, 1384/10/20

Ethics committee reference number

28/20/2635

Health conditions studied

1

Description of health condition studied

Bed sore

ICD-10 code

L89

ICD-10 code description

Decubitus ulcer

Primary outcomes

1

Description

Bed sore size (square cm)

Timepoint

Before intervention and every 48 hours for 4 weeks

Method of measurement

with sterilized ruler (scaled abslang)

Secondary outcomes

empty

Intervention groups

1

Description

Irrigation of ulcer by normal saline solution, topical hyperbaric oxygen 10 l/min with catheter for 20 min and then dressing by adequate sterile dry gauze, 3 times a day.

Category

Treatment - Other

2

Description

Irrigation of ulcer by normal saline solution, and then dressing by adequate sterile dry gauze, 3 times a day

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Boali Hospital

Full name of responsible person

Dr Zohal

Street address

Boali Hospital, Boali St.

City

Qazvin

2

Recruitment center

Name of recruitment center

Rajaii Hospital

Full name of responsible person

Dr Ebrahimi

Street address

Rajaii Hospital, Padegan St.

City

Qazvin

3

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Dr Shokouhossadat Abootorabi

Street address

Kosar Hospital, Valiasr St.

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zahra kalantari

Street address

Qazvin University of Medical Sciences

City

Qazvin

Grant name

229

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

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Full name of responsible person

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Position

M.A degree, PhD student

Other areas of specialty/work

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Web page address

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