

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of topical Olive oil on prevention of bed sore in ICU patients at educational -medical hospitals of Qazvin .

Protocol summary

Summary

Objectives are: to determine the effect of topical Olive oil on prevention of bed sore; to determine the frequency distribution of bed sore; to determine the mean duration of not developing bed sores; to determine demographic characteristics associated with bed sore. Design: this research is an experimental study of the randomized clinical trial with control group. Setting and conduct: The control group is received skin care includes changing positions every 2 hours and floating mattress (the standard treatment that in all centers are only included this) and the intervention group in addition to standard therapy, receive topical Olive oil. Participants: 60 eligible patients were randomly selected and with main inclusion criteria: having 18 years of age and older; lack of bed sores and the main exclusion criteria: the incidence of any sensitivity due to using of Olive oil be in two groups. Intervention: Famila labeled virgin Olive oil with Standard sign has been prepared, which once a day and each time 15 cc of it is gently and without massage applied on under pressure areas of the body. Selected patients receive topical Olive oil for three weeks and every 24 hours the skin care area is evaluated by the investigator and occurrence or non-occurrence of bed sores grade 1-4 in these areas is recorded in questionnaire. It also is stipulated that the two groups do not use any creams or other oil on the area. Main outcome variables: bed sore; applying topical Olive oil; duration of lack of developing bed sores.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111014634N2**

Registration date: **2014-02-20, 1392/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-20, 1392/12/01

Registrant information

Name

Zahra Abbas Ali Madadi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 1367 6284

Email address

zabbasalimadadi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2014-01-20, 1392/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical Olive oil on prevention of bed sore in ICU patients at educational -medical hospitals of Qazvin .

Public title

Effect of topical Olive oil on prevention of bed sore in intensive care unit patients

Purpose

Prevention

Inclusion/Exclusion criteria

Major inclusion criteria: having 18-90 years old; lack of skin problems; lack of bedsores; no history of diabetes; no history of sensitivity to the Olive and Olive products; having a Foley catheter. Major exclusion criteria: the incidence of any sensitivity due to using of Olive oil; lack of consent of guardians and sample to continue to participate in the study; transferring the patient to another center outside the city of Qazvin; the patient dies; observing any Sign of skin problems (rash, hives, redness, swelling, ulcers).

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin

City

Qazvin

Postal code

3419759811

Approval date

2012-12-05, 1391/09/15

Ethics committee reference number

6643/20/3

Health conditions studied

1

Description of health condition studied

Bedsore

ICD-10 code

L89

ICD-10 code description

Decubitus ulcer and pressure area

Primary outcomes

1

Description

Bedsore

Timepoint

Once every 24 hours

Method of measurement

Skin areas is observed and evaluated by the investigator and the occurrence or non-occurrence of bedsores grade 1-4 in these areas is recorded in questionnaire.

2

Description

Applying topical Olive oil

Timepoint

Once every 24 hours

Method of measurement

Based on yes or no is recorded in the questionnaire

3

Description

Duration of lack of developing bedsores

Timepoint

Once every 24 hours

Method of measurement

Based on day is recorded in the questionnaire

4

Description

Age

Timepoint

First meeting of evaluation

Method of measurement

Based on year is recorded in the questionnaire

5

Description

Sex

Timepoint

First meeting of evaluation

Method of measurement

Based on sex is recorded in the questionnaire

6

Description

Weight

Timepoint

First meeting of evaluation

Method of measurement

Based on Kilogram is recorded in the questionnaire

7

Description

Amount of mobility

Timepoint

Once every 24 hours

Method of measurement

Based on Braden scale is recorded in the questionnaire

8

Description

Defecation control

Timepoint

Once every 24 hours

Method of measurement

Based on yes or no is recorded in the questionnaire

9

Description

Position of head of bed

Timepoint

Once every 24 hours

Method of measurement

Based on degree is recorded in the questionnaire

10

Description

Height

Timepoint

Once every 24 hours

Method of measurement

Based on Meter and Centimeter is recorded in the questionnaire

11

Description

Taking Carbamazepine, Co-trimoxazole and Largactil

Timepoint

Once every 24 hours

Method of measurement

Based on yes or no is recorded in the questionnaire

Secondary outcomes

1

Description

Duration of ICU hospitalization

Timepoint

Once at the end of ICU hospitalization

Method of measurement

Based on day is recorded in the questionnaire

Intervention groups

1

Description

The control group is received skin care includes changing position every 2 hours and floating mattress (the standard treatment that in all centers are only included this).

Category

Prevention

2

Description

The intervention group in addition to changing positions every 2 hours and floating mattress (standard therapy), receive topical Olive oil. Famila labeled virgin Olive oil with Standard sign has been prepared, which once a day and each time 15 cc of it is gently and without massage applied on Pinna, Shoulders, Spine, Waist, Buttocks, Iliacs and Sacrum, Elbows, Heels and Ankles areas. Selected patients receive topical Olive oil for three weeks and every 24 hours the skin care area is observed and evaluated by the investigator and occurrence or non-occurrence of bedsores grade 1-4 in these areas is recorded in questionnaire. It also is stipulated that the two groups do not use any creams or other oil on the area. Meanwhile, the two groups is matched by age and sex.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

ICU sections of educational - medical hospitals of Qazvin

Full name of responsible person

Zahra Abbas Ali Madadi master student of intensive care nursing

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of Medical Sciences

Full name of responsible person

Dr. Zeinab Jourabchi

Street address

Qazvin University of Medical Sciences, Shahid

Bahonar Boulevard, Qazvin

City

Qazvin

Grant name

Grant code / Reference number

28/6/7309

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

Yes

Title of funding source

Vice chancellor for research, 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

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Abbas Ali Madadi

Position

Master student of intensive care nursing

Other areas of specialty/work

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin

City

Qazvin

Postal code

3419759811

Phone

+98 28 1367 6284

Fax

+98 28 1223 7268

Email

madadi_z20@yahoo.com

Web page address

www.qums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Reza Zeighami

Position

PHD

Other areas of specialty/work

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin

City

Qazvin

Postal code

3419759811

Phone

+98 28 1333 8127

Fax

+98 28 1223 7268

Email

behsare@yahoo.com

Web page address

www.qums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Abbas Ali Madadi

Position

Master student of intensive care nursing

Other areas of specialty/work

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Boulevard, Qazvin

City

Qazvin

Postal code

3419759811

Phone

+98 28 1367 6284

Fax

+98 28 1223 7268

Email

madadi_z20@yahoo.com

Web page address

www.qums.ac.ir

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