

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effectiveness of Rosemary ointment on Improving of pressure ulcer stage 1 in hospitalized patient of Intensive care unit

Protocol summary

Study aim

Investigating the effect of Rosemary topical ointment on bedsore grade I in hospitalized patient in ICU of Ali-ebn-abitalib hospital; 2018

Design

Clinical trial with control group, Community based and pragmatic, with parallel groups, blinded postoperative care, randomized

Settings and conduct

In this study, the effect of rosemary ointment on the size of the patient's pressure ulcer in the intensive care unit was investigated. In this study, the evaluator did not know how to grouping.

Participants/Inclusion and exclusion criteria

Age over 20 years Lack of diabetes No use of corticosteroids Patients are motionless Patients have moderate to severe decrease levels of consciousness

Intervention groups

Intervention group: Application of rosemary ointment
Control group: No application of Rosemary ointment

Main outcome variables

pressure ulcer size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160503027736N3**
Registration date: **2018-06-10, 1397/03/20**
Registration timing: **prospective**

Last update: **2018-06-10, 1397/03/20**

Update count: **0**

Registration date

2018-06-10, 1397/03/20

Registrant information

Name

shahin heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 5351

Email address

sh.heidari@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of Rosemary ointment on Improving of pressure ulcer stage 1 in hospitalized patient of Intensive care unit

Public title

Investigating the effect of Rosemary ointment on bedsore grade 1

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 40 years The absence of skin disorders such as dermatitis Moderate and severe alertness

Exclusion criteria:

Discharge with personal consent Failure to cooperate for any reason during the study Progress towards pressure

ulcer stage 2

Age
From **20 years** old to **90 years** old

Gender
Both

Phase
0

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
The intervention group was recruited from the patients admitted to the intensive care unit with pressure ulcer stage I, in a sample size (n=35) in convenience method. Then, they will be classified according to the Body mass index (equal and less than 25 and above 25) and the age (20-40 years, 41-60 years, 61-90 years). The control group according to the Body mass index and age classification of the intervention group, was selected from among the patients admitted to the intensive care unit with the pressure ulcer stage I with convenience method.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the evaluator of bed sore size is not aware of patient grouping.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee in medical researches

Street address
Imam Ali

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Approval date

2017-12-21, 1396/09/30

Ethics committee reference number

IR.RUMS.REC.1396.208

Health conditions studied

1

Description of health condition studied

Bed sore

ICD-10 code

L89

ICD-10 code description

Pressure ulcer

Primary outcomes

1

Description

Ulcer area

Timepoint

Everyday until 7 days

Method of measurement

Ruller

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the length and width of the pressure ulcer will be measured first by the ruler. Then, the wound is wiped with 100 cc normal saline solution, 0.9% sterile non-injectable. After drying with sterilized gauze, the Rosemary ointment 30 grams made by Iranian GOLDARU Company (Isfahan, Iran), with a thickness of 2-3 mm, is placed on a 8-layer sterile gauze. Then, the ointment impregnated gauze is placed on a pressure ulcer and glued to the healthy skin with a paper anti-allergenic adhesive. This process takes place once a day for 7 days. On the third and seventh day after the application of the ointment, the extent of the wound will be measured with the same ruler. The size of the wound will be classified using the pressure ulcer scale for healing tool (PUSH) from 0 to 10. Zero means no wound, and number 10 means a wound with more than 24 Square centimeters. Finally, the three scores of different stages of measurement, will be compared.

Category

Treatment - Drugs

2

Description

Control group: In this study, rosemary topical ointment will not be used for any control group, and they will receive routine cares.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان علی ابن ابیطالب

Full name of responsible person

Fatemeh Khoshoei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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alishamsy@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Heidari Shahin(PHD)

Position

PHD of nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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
 Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan
 Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
 Yes - There is a plan to make this available

Clinical Study Report
 Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
 Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
 Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
 Age, Gender, hemoglobin, haematocrit, and the main outcome can be expressed

When the data will become available and for how long
 2019

To whom data/document is available
 Universities researchers

Under which criteria data/document could be used
 For research, by submitting a valid academic Demand

From where data/document is obtainable
 Vice chancellor for research & technology

What processes are involved for a request to access data/document
 Submitting a written request to the Rafsanjan University of medical sciences, Vice chancellor for research, agreeing to study colleagues

Comments