

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison the effect of Hydrocolloid dressing and Boswellia gel in healing of bed sore in patients.

Protocol summary

Study aim

Determination of the effect of Boswellia gel and hydrocolloid dressing on second and third degree pressure ulcer repair in hospitalized patient.

Design

This clinical trial has three groups. The groups are parallel, double-blinded, randomized, each group size is 25.

Settings and conduct

The research population are patients with second and third degree ulcer selected by simple sampling method. The place of intervention is Shahid Faghihi hospital of Shiraz. The number of patients in each group is 25. In this study, the wound assessor and patients are unaware of the type of intervention. Patients are treated for 35 days. The wounds are scored on the wound healing process on the first, 7th, 14th and 21th, 28th and 35th days.

Participants/Inclusion and exclusion criteria

Age over 18 years. Second-degree and three-degree pressure ulcer. Hospitalized patients. Matched used antibiotics. Not having inflammatory disease.

Intervention groups

The study consists of three groups: First intervention group, They are treated with hydrocolloid dressing and Boswellia gel. Second intervention group, They are treated with hydrocolloid dressing and Plasebo gel. control group, They are treated with hydrocolloid dressing.

Main outcome variables

Size of the Bed sore; wound tissue score; amount of bed sore discharge; transforming growth factor beta 1 and beta 3

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181024041449N1**

Registration date: **2018-11-22, 1397/09/01**

Registration timing: **retrospective**

Last update: **2018-11-22, 1397/09/01**

Update count: **0**

Registration date

2018-11-22, 1397/09/01

Registrant information

Name

ali hassanpourdehkordi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 38 3334 6720

Email address

alihassanpourdehkordi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-30, 1396/10/09

Expected recruitment end date

2018-07-05, 1397/04/14

Actual recruitment start date

2017-12-30, 1396/10/09

Actual recruitment end date

2018-07-05, 1397/04/14

Trial completion date

2018-07-05, 1397/04/14

Scientific title

Comparison the effect of Hydrocolloid dressing and Boswellia gel in healing of bed sore in patients.

Public title

Boswellia in wound healing.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having second and third grade of bed sore. Age over 18 years. Hospitalized patients. Not having inflammatory disease. Uniformity of antibiotic use.

Exclusion criteria:

Patient death. Unwillingness to cooperate. Skin allergy reaction.

Age

From **18 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **75**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. Patients randomly take one card from inside a box in which are cards with letters A, B, C with the same number of samples.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient does not know that is in which group. The evaluators are unaware of the type of intervention performed in the patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Shahrkord University Of Medical Sciences

Street address

University Of Medical Sciences, Rahmatie, Shahrkord Town.

City

Shahrkord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2017-09-10, 1396/06/19

Ethics committee reference number

IR.SKUMS.REC.1396.142

Health conditions studied

1

Description of health condition studied

Bed sore stage II

ICD-10 code

L89.1

ICD-10 code description

bed sore stage II

2

Description of health condition studied

Bed sore stage III

ICD-10 code

L89.2

ICD-10 code description

Bed sore stage III

Primary outcomes

1

Description

Pressure ulcer healing

Timepoint

At the beginning of the study, 7, 14, 21, 28 and 35 days after the beginning of dressing.

Method of measurement

Pressure Ulcer Scale for Healing, (PUSH TOOL)

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: On the first day of the intervention and days of 7, 14, 21, 28 and 35, patients are treated with Boswellia gel 5% and hydrocolloids dressing. During the above periods, the wounds are scored with the Push tools. At the end of the intervention, the wound healing process is evaluated by comparing the scores of the wounds.

Category

Treatment - Drugs

2

Description

Second Intervention group: On the first day of the intervention, 7, 14, 21, 28 and 35 were treated with

placebo gel and hydrocolloids dressing. During the above periods, the wounds were scored with the Push tools. At the end of the intervention, the wound healing process is examined.

Category

Placebo

3**Description**

Control group: On the first day of the intervention and 7, 14, 21, 28 and 35, patients are treated with hydrocolloids dressing. During the above periods, the wounds are scored with the Push tools. At the end of the intervention, the wound healing process is evaluated by comparing the scores of the wounds.

Category

Treatment - Drugs

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

Shahid Faghihi Hospital

Full name of responsible person

Ali Hassanpour Dehkordi

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Shiraz, Zand Blv, Shahid Faghihi Hospital.

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

Shahre-kord University of Medical Sciences

Full name of responsible person

Ali Hassanpour Dehkordi

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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

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**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Ali Hassanpour Dehkordi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Observe the anonymity and confidentiality of the participants' information.

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable