

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of herbal ointment including *Plantago major* L and *Rosa damascene* on the bed sore of hospitalized patient

Protocol summary

Study aim

Determination of effect of herbal ointment including *Plantago major* L and *Rosa damascene* on bed sore.

Design

The study is a community-based randomized clinical trial with parallel design (intervention and control), double blind controlled, randomized, one step. Sample size 100 (50 individuals per group) in which Individuals will be assigned into the intervention or control groups using a random number table (as a tool of randomization).

Settings and conduct

The subjects were patients with bed sores in Khomein city who have grade 2 and grade 3 ulcers. Blindness in this study was double-blind, so that the participant and researcher evaluated the outcome were not aware of allocation of the patients under study. In this study, the repair of compression wounds was compared with the two methods including dressing with herbal ointment (honey, *Plantago major* L and *Rosa damascene*) and dressing with Comfeel. Wound dressing in both groups were done under equal conditions (how many times the dressing is changed in 24 hours, the duration and manner of washing). PUSH is used as a data gathering tool. Before and after 4 weeks of intervention, the tool was measured and its scores were compared between two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years old; having 2nd and 3rd grade pressure ulcers. Exclusion criteria: Any allergy to the use of plants; sores containing pus; bone involvement; bone visibility; sepsis due to wound infections.

Intervention groups

Intervention group: Intervention included placement of a layer of herbal ointment include *Plantago major* L and *Rosa* after washing and scrubbing the ulcer and covering with a layer of sterile gas. Control group: placing a layer of Comfeel on the wound after washing and cleaning the wound and covering with a sterilized gas.

Main outcome variables

Wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100130003227N13**

Registration date: **2019-05-24, 1398/03/03**

Registration timing: **retrospective**

Last update: **2019-05-24, 1398/03/03**

Update count: **0**

Registration date

2019-05-24, 1398/03/03

Registrant information

Name

Ashraf Salehi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2018-07-23, 1397/05/01
Trial completion date
 2019-04-17, 1398/01/28

Scientific title
 Comparison of the effect of herbal ointment including Plantago major L and Rosa damascene on the bed sore of hospitalized patient

Public title
 The effect of herbal ointment including Plantago major L and Rosa damascene on bed sore.

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Being at the age of over 18 years old having 2nd and 3rd grade pressure ulcers the same antibiotic use in all patients
Exclusion criteria:
 any susceptibility to the use of herbs certain vascular damage such as Burger disease the presence of combined skin problems. bone involvement bone visibility sepsis caused by wound infections malignancy connective tissue disease Vasculitis known case of immune system disorders Corticosteroid use chemotherapy radiotherapy

Age
 From **18 years** old

Gender
 Both

Phase
 2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
 Target sample size: **40**
 Actual sample size reached: **100**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Individuals will be assigned into the intervention or control groups using a random numbers table.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Participants will be blinded for allocation into intervention or control groups due to randomization and will not be informed about the intervention type (Dressing with herbal ointment combing honey, tufted bell pepper and spinach or dressing with Comfeel, which is commonly used to repair bed litter.) before study initiation. Outcome assessors will not be informed about the patients categorization.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Khomain University of Medical Sciences

Street address

Qods Blvd

City

Khomein

Province

Markazi

Postal code

38817-43364

Approval date

2018-03-18, 1396/12/27

Ethics committee reference number

IR.KHOMEIN.REC.1397.003

Health conditions studied

1

Description of health condition studied

Bed sore

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Wound healing score according to the PUSH tool

Timepoint

Before and after 4 weeks of intervention

Method of measurement

PUSH tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention consists of placing a layer of herbal ointment consisting of honey, Plantago major L and Rosa damascene on the wound (bed sore) to the required amount (based on the size, amount and type of secretion of the wound), after washing and scrubbing (rinsing with 0.9% normal serum serum) Which was covered with a layer of sterilized gas. Wound dressing was carried out in both groups under equal

conditions (number of dressing changes in 24 hours, duration and manner of washing). In this study, to prepare this ointment, 1.5 grams of the Plantago major L in 25 ml of water and 1 g of the Rosa damascene in 25 ml of water are brewed and mixed with 50 g of honey and For every dressing, was used. After preparing the ointment, pouring some ointment in a can for each patient and labeling the name of each patient on the can were done. Dressing was done by two trained observer (one man and one female) about the method of dressing the bed sore, one to three times a day (depending on the condition of the wound) until complete wound healing. Observers took an observation measure (PUSH: pressure ulcer score for healing) before the intervention and then every week at a specified hour to determine the instrument scores. The Braden tool was used to control the confounding factors such as patient mobility, sensory perception, skin moisture, degree of physical activity, and nutritional status of patients.

Category

Treatment - Other

2

Description

Control group: The intervention involves placing a layer of Comfeel on the wound (bed sore) to the required amount (based on the size, amount and type of secretion of the wound), after washing and scrubbing (rinsing with 0.9% normal serum serum) Which was covered with a layer of sterilized gas. Wound dressing was carried out in both groups under equal conditions (number of dressing changes in 24 hours, duration and manner of washing). Dressing was done by two trained observer (one man and one female) about the method of dressing the bed sore, one to three times a day (depending on the condition of the wound) until complete wound healing. Observers took an observation measure (PUSH: pressure ulcer score for healing) before the intervention and then every week at a specified hour to determine the instrument scores. The Braden tool was used to control the confounding factors such as patient mobility, sensory perception, skin moisture, degree of physical activity, and nutritional status of patients.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Mohammad Taheri

Street address

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rheum.nursing@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khomein University of Medical Sciences

Full name of responsible person

Javad Javaheri

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Phone

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Email

Javad.javaheri@khomeinums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khomein 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

Khomein University of Medical Sciences

Full name of responsible person

Mohammad Taheri

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Ashraf Salehi
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Other areas of specialty/work
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Person responsible for updating data

Contact

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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

There is no more data.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

A large amount of data, such as information on the main outcome, how to do it, and ... can be shared.

When the data will become available and for how long

Accessible 6 months after printing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

By observing ethics in research

From where data/document is obtainable

Hamid Momeni hamid52us@yahoo.com

What processes are involved for a request to access data/document

Sending the request to the email and waiting for the answer; applicant's authentication; sending an answer or response to the applicant after a scientific and ethical verification within a maximum of two weeks.

Comments