

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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)

##### Phone

+98 86 5222 7550

##### Email address

salehi.a@arakmu.ac.ir

##### 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

Qods Blvd

##### City

Khomein

##### Province

Markazi

##### Postal code

38817-43364

##### Phone

+98 86 4633 2211

##### Email

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

##### Street address

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##### City

Khomein

##### Province

Markazi

##### Postal code

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##### Phone

+98 86 4622 1533

##### 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

Nursery

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Khomein University of Medical Sciences  
**Full name of responsible person**  
Ashraf Salehi  
**Position**  
Faculty member  
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Master  
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najm54@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Khomein University of Medical Sciences  
**Full name of responsible person**  
Hamid Momeni  
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Faculty member  
**Latest degree**  
Master  
**Other areas of specialty/work**

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hamid52us@yahoo.com

## 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