

# 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)

###### Phone

+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

**Street address**

Shiraz, Zand Blv, Shahid Faghihi Hospital.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

+98 71 3235 1087

**Fax**

+98 71 3233 1634

**Email**

faghihihsp@sums.ac.ir

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

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Ali Hassanpour Dehkordi

**Street address**

Shahre-kord University Of Medical Sciences, Rahmatie, Shahrkord.

**City**

Shahre-kord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8815713471

**Phone**

+98 38 3333 0061

**Email**

info@skums.ac.ir

**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

**Street address**

Shahre-kord University Of Medical Sciences, Rahmatie, Shahrekord

**City**

Shahre-kord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8815713471

**Phone**

+98 0383333061

**Email**

Alihassanpourdehkordi@skums.ac.ir

**Person responsible for scientific 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  
**Street address**  
Shahrekord University Of Medical  
Sciences,Rahmatie,Shahrekord.

**City**  
Shahrekord

**Province**  
Chahar-Mahal-va-Bakhtiari

**Postal code**  
8815713471

**Phone**  
+98 38 3333 0061

**Email**  
alihassanpourdehkordi@skums.ac.ir

## Person responsible for updating data

### 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

**Street address**  
Shahrekord University Of Medical Sciences, Rahmatie,  
Shahrekord

**City**  
Shahrekord  
**Province**  
Chahar-Mahal-va-Bakhtiari

**Postal code**  
8815713471

**Phone**  
+98 38 3333 0061

**Email**  
alihassanpourdehkordi@skums.ac.ir

## 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