

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of topical cream containing zataria multiflora, Pelargonium graveolens and aloe vera gel on size, tissue type and exudate of bed sore on beheshti hospital patients

#### Protocol summary

##### Summary

This double-blind controlled study as a clinical trial on patients with grade 1 and 2 bed sore will be done. Qualified individuals for entry who do not have exclusion criteria use in the project including underlying medical condition, medications and allergies to ingredients, randomly will divide into two groups receiving herbal gel or placebo gel. The two topical products by Barij Essence Company in packaging with the same color and size are made and so patients and physicians won't be aware of the type of medicine. And after completion of the project components will be decoded. So this study will be a double blind study. Duration of study is one month. In these period individuals, 2 times daily after washing with normal saline, use a thin layer of topical components with dressing. At the baseline and end of each week features of Ulcer according to the criteria PUSH will be reviewed. After data collection, the t-test is used to compare groups; also the effect of different parameters is carried out by using analysis of repeated measurements

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013072912438N4**  
Registration date: **2013-08-21, 1392/05/30**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-08-21, 1392/05/30

##### Registrant information

Name

Mohsen Taghizadeh

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 36 1555 0021

##### Email address

taghizadeh\_m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Barij Essence research center of medicinal herbs

##### Expected recruitment start date

2013-08-23, 1392/06/01

##### Expected recruitment end date

2014-03-21, 1393/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of topical cream containing zataria multiflora, Pelargonium graveolens and aloe vera gel on size, tissue type and exudate of bed sore on beheshti hospital patients

##### Public title

Treatment of bed sore

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: All patients with bed sores Exclusion criteria: cardiovascular diseases, malignancies, end-stage disease - systemic or topical antibiotics - taking

glucocorticoids and other local and systemic immunosuppressant drugs - other chronic cutaneous illnesses- sensitivity of herbal products-Desire to withdraw from the study.

**Age**

No age limit

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **102**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Kashan university of medical sciences

**Street address**

Kashan university of medical science, Kashan

**City**

Kashan

**Postal code****Approval date**

2013-07-23, 1392/05/01

**Ethics committee reference number**

1701/1/5/29

**Health conditions studied****1****Description of health condition studied**

bedsore

**ICD-10 code**

L89

**ICD-10 code description**

Decubitus ulcer and pressure area

**Primary outcomes****1****Description**

Length x Width

**Timepoint**

end of each week

**Method of measurement**

greatest lengthx greatest width with ruler

**2****Description**

exudate amount

**Timepoint**

end of each week

**Method of measurement**

observation

**3****Description**

tissue type

**Timepoint**

end of each week

**Method of measurement**

observation

**Secondary outcomes**

empty

**Intervention groups****1****Description**

intervention group:topical herbal cream- 2 times a day on the bed sore + routine Dressing

**Category**

Treatment - Drugs

**2****Description**

control group:topical alfa cream- 2 times a day on the bed sore + routine Dressing

**Category**

Placebo

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

Shahid Beheshti Hospital

**Full name of responsible person**

dr. H.afzali

**Street address**

Shahid Beheshti Hospital, Kashan

**City**

Kashan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Barij Essence research center of medicinal herbs

**Full name of responsible person**

miss L.Hejazi

**Street address**

km44 Kashan, Mashhad Ardehal road.

**City**

Kashan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Barij Essence research center of medicinal herbs

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

M.Taghizadeh

**Position**

PhD

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Barij Essence Research Center of Medicinal Herbs

**Full name of responsible person**

M.Mahlouji

**Position**

Expert in clinical research

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*