

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

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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 updating data

Contact

Name of organization / entity

Barij Essence Research Center of Medicinal Herbs

Full name of responsible person

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Expert in clinical research

Other areas of specialty/work

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Web page address

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