Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the Effectiveness of Arnebia euchroma Ointment and Silver nanoparticles dressing on pain and Pressure Ulcer healing

Protocol summary

Study aim
Evaluation Effects Of Arnebia euchroma Ointment with Silver nanoparticles Dressing on Pressure Ulcer Pain and its Healing

Design
This study is a Randomized controlled clinical trial with parallel groups and single-blinded.

Settings and conduct
The Research sample size consists of 60 patients with grade 2,3 and 4 Pressure ulcers (intervention group30, control group 30) admitted to Khatam and Aliebene-Abi-Taleb hospitals in Zahedan city in 2022- 2023

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years. Second-degree, Three-degree, and Four-degree Pressure ulcers. Hospitalized patients. Normal Serum Albumin Levels, Nonverbal communication. Exclusion Criteria: Alcoholism, Immune system failure, liver failure, Not having a wavy mattress

Intervention groups
The Intervention in this study is using the Arnebia euchroma Ointment. In the control group, the intervention uses Silver nanoparticles dressing. The wound will be checked by push-scale on days 1,7,12 and the pain of change dressing will be checked by a nonverbal pain scale

Main outcome variables
The Healing rate of Pressure ulcer

General information

Reason for update
Completion of clinical trial

Acronym

IRCT registration information
IRCT registration number: **IRCT20220308054222N1**
Registration date: **2022-08-02, 1401/05/11**
Registration timing: **prospective**
Last update: **2024-04-17, 1403/01/29**
Update count: **1**

Registration date
2022-08-02, 1401/05/11

Registrant information

Name
Sajjad Mohammadzade sarhadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3222 3933

Email address
sajjad.0596@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-16, 1401/05/25

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
2022-09-23, 1401/07/01

Actual recruitment end date
2023-05-20, 1402/02/30

Trial completion date
2023-05-20, 1402/02/30

Scientific title
Comparison of the Effectiveness of Arnebia euchroma Ointment and Silver nanoparticles dressing on pain and Pressure Ulcer healing

Public title
A Survey of the effectiveness of Arnebia euchroma Ointment and Silver nanoparticles dressing on pain and Pressure Ulcer healing

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with pressure ulcers grade 2 ,3 and 4 nonverbal patient Using a wavy mattress Albumin level above 3 mg/dL Presence of pain in the area

Exclusion criteria:

A history of any allergy to Arnebia euchroma and silver Use of other dressings during the intervention

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization is first done by random sequence generation. A simple randomization method will be used to generate a random sequence. The method of simple randomization in this study is the use of a random number table. A random number table is a set of numbers that are generated without a specific pattern or order and in a completely random form and has become a table. In order to use the table of random numbers, we first preset the table to read the numbers (from left to right). Then the numbers are considered for the study groups so that even numbers will be considered for the experimental group and odd numbers will be considered for the control group. The second step is the concealment of the randomization allocation because the assigned group will not be specified before the individual is assigned. In this study, due to the fact that sampling is multicenter, the central randomization method will be used to hide the allocation. In this method, the random sequence is given to a person in the school of Nursing and sampling is performed in two centers. Based on the order in which the participants entered the study, the researcher contacted the mentioned person in the School of Nursing and asked about the random assignment of the participant to the experimental or control group. Communication method include the use of telephone.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is Single blind. The outcome evaluator don't knows the groups and is unaware of type of treatment in each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

ZAUMS Main campus, Zahedan, Sistan and Baluchestan, Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2022-07-24, 1401/05/02

Ethics committee reference number

IR.ZAUMS.REC.1401.140

Health conditions studied

1

Description of health condition studied

pressure ulcer

ICD-10 code

L89

ICD-10 code description

Pressure ulcer

Primary outcomes

1

Description

Wound Healing

Timepoint

The first, seventh, and twelfth day

Method of measurement

Pressure Ulcer Scale for Healing (PUSH Tool)

2

Description

Pain

Timepoint

The first, seventh, and twelfth day

Method of measurement

Nonverbal Pain Scale (NVPS)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: For 12 days, After Washing the Wound with Sodium Chloride Irrigation Solution 0.9%, the Wound is Dressed with Silver nanoparticle Dressing (AGICOAT) Once Every Three Days. And on the First, Seventh, and Twelfth Days, The Condition of The Wound and the Level of Pain Experienced Will be Measured.
Category
Treatment - Drugs

2

Description
Intervention group: For 12 days, After Washing the Wound with Sodium Chloride Irrigation Solution 0.9%, the Wound is Dressed with Arnebia Euchroma Ointment (GOUROH Ointment) and Sterile Gauze Pads Once Every Two Days. And on the First, Seventh, and Twelfth Days, The Condition of The Wound and the Level of Pain Experienced Will be Measured.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Aliebneabitaleb Hospital
Full name of responsible person
sajjad mohammadzade
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Persian gulf Blvd. Aliebeneabitaleb hospital
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Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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ZAUMS, Main campus, Khalij_e_Fars Blvd, Zahedan, Sistan & Baluchestan, Iran
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research@zaums.ac.ir
Web page address
https://www.zaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Sajjad Mohammadzade
Position
nurse

Latest degree
Master
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Person responsible for updating data

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mohammadzadehs911@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Part of the data is related to the main outcome and the secondary outcome can be shared.
When the data will become available and for how long
The access period starts 3 months after the results are published
To whom data/document is available
The data is available to researchers working in academic and scientific institutions as well as people working in the industry.
Under which criteria data/document could be used
Use as a reference
From where data/document is obtainable
DR.Simin sharifi, siminsharifi1@gmail.com
What processes are involved for a request to access data/document
After making a call via email or phone, the desired data will be sent using email or post.
Comments