Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of 5% root extract of Arnebia euchroma Ointment on pressure sore

Protocol summary

Study aim
The effect of Arnebia euchroma ointment on accelerating bed sore healing

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 20 patients.

Settings and conduct
Patients are among those with pressure sores who are cared for in a nursing home or home or are selected from patients referred to medical centers. Participants, researchers and nurses are not aware of the type of ointment used and the final results are reported without knowing the type of drug used.

Participants/Inclusion and exclusion criteria
The statistical population of the present study includes patients with pressure sores and 20 patients with grade 1, 2 and 3 pressure sores will be included in the study. Patients with bed sores of grade 4, patients with wounds other than pressure sores such as infectious wounds, etc.,hypersensitivity to the Arnebia euchroma , patient dissatisfaction, diabetic patients, patients with wound healing disorders and patients who are unable to feed orally are excluded from the study.

Intervention groups
Patients are divided into two groups: one group uses standard treatment (silver sulfadiazine ointment) and the other group uses ointment containing 5% root of Arnebia euchroma plant.

Main outcome variables
Since no systematic study has been done on the effects of this plant on bed sores; The aim of this study was to evaluate the effect of Abu Khalsa ointment on bed sores. We evaluate bed sores according to the amount of discharge, depth of the wound, diameter or area of the wound, and erythema.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170818035762N4**
Registration date: **2023-01-17, 1401/10/27**
Registration timing: **retrospective**

Last update: **2023-01-17, 1401/10/27**
Update count: **0**

Registration date
2023-01-17, 1401/10/27

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 4221 8021
Email address
a.kazeminejad@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-09, 1399/08/19

Expected recruitment end date
2021-03-09, 1399/12/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of 5% root extract of Arnebia euchroma Ointment on pressure sore

Public title

The effect of Arnebia euchroma on pressure sore

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with grade 1 and 2 and 3 pressure sore

Exclusion criteria:

Patient with grade 4 pressure sore Patients with wounds other than pressure wounds such as infectious wounds and ... Hypersensitivity to Arnebia euchroma Patient dissatisfaction Diabetic patients Patients with wound healing disorders Patients who are unable to feed orally

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization list is prepared by a person who is not present in the study. The randomization method will be based on the "balanced block randomization" method, in such a way that the number of people who will participate in the study, in the order of entering the study, will be divided into blocks whose size is determined by the person in question. This number will remain hidden so that the people present in the study are not aware of the size of the blocks. Allocation of each person in each block is done equally between two groups by generating random numbers in Excel software. For example, if the size of the block is 4, in the Excel software, 2 codes A and 2 codes B are written in 4 rows, and a random number is created in front of each one, and by sorting these 4 rows based on the generated random numbers, the codes A and B will be randomly assigned to the people of this special block. This is done for other blocks as well. Allocation of codes A and B to intervention and control will be done randomly by a third party and will be reopened after analyzing the data and summarizing the results. Based on the random allocation list, the third person writes numbers from one to n (sample size) on the uniform packages of ointments, and in this way, the participants in the study and the researchers will not be aware of the contents of the packages and the grouping of A and B. The random allocation list will be reopened after data collection is completed to determine the two study groups for statistical analysis.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this intervention, Arnebia euchroma ointment and silver sulfadiazine ointment are available, and the blinding procedure is such that the ointments containing Arnebia euchroma and silver sulfadiazine ointments are placed in the same package and coded by a third party, and then available to the training nurse. is seen The participants, the main researcher (who is also responsible for the care of the patients) and the data analyst will not know about the content of the ointments.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, at the beginning of Valiasr Highway, Joibar three ways, Imam Square, Sari, Mazandaran Province

City

sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2021-01-24, 1399/11/05

Ethics committee reference number

IR.MAZUMS.REC.1399.8246

Health conditions studied

1

Description of health condition studied

Pressure sore

ICD-10 code

L89

ICD-10 code description

Pressure ulcer

Primary outcomes

1

Description

Changing the condition of the bed sore

Timepoint

Before the intervention and then every week until the lesion heals

Method of measurement
By viewing images taken from the affected area

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Hava Chubeh (Abu Khalsa) is a herbaceous plant, stable and covered with coarse fibers. The part used by this plant is its root, which contains various compounds such as alkanin and chiconin. Alkanin or oncosine is a pigment with the formula C16H16O5 with a molecular weight of 228.29. It is dissolved in aqueous solutions, chloroform, acetic acid and in various oils. Its right-handed form is called chiconin and its racemic form is called chicalkine.First, the wound site is washed with normal saline serum, then the wound is covered with a suitable amount of ointment that contains 5% of the root of Abu Khalsa plant (Hawoobeh) to a thickness of one millimeter so that the wound surface is completely covered. Then, by placing a prepared pad or gasoline on the wound, the position is bandaged. This process is continued once every 12 hours according to the amount of discharge until complete healing.Ointment is produced in 50 g tubes by Amir Giah Amir Company in Barij Essential Oil Company.
Category
Treatment - Drugs

2

Description
Control group: First, the wound site was washed with normal saline, then the wound was covered with a suitable amount of silver sulfadiazine ointment to a thickness of mm so that the wound surface was completely covered. Then, by placing a prepared pad or gauze on the wound, the position is bandaged. All steps are performed by a trained nurse. The dressing is opened after 12 hours and the mentioned steps are repeated. This process is continued once every 12 hours according to the amount of wound secretion until complete healing. The ointment is produced in 50 g tubes by Amir Giaat Company in Barij Essential Oil Company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sari Buali Sina Hospital
Full name of responsible person
Armaghan Kazeminejad
Street address
Buali Sina Hospital.First of Ghaemshahr road.Sari
City
sari
Province
Mazandaran
Postal code
۳۳۹۷۱۴۸۱۵۷
Phone
+98 11 3304 4001
Email
publicrel@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Majid Saeedi
Street address
Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari
City
Ŝari
Province
Mazandaran
Postal code
4414733971
Phone
+98 11 3304 4001
Email
publicrel@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr.ArMarghan Kazeminejad
Position
Associate professor

Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3304 4001
Email
A.kazeminejad@mazums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr.ArMarghan Kazeminejad
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3304 4001
Email
A.kazeminejad@mazums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr.ArMarghan Kazeminejad
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3304 4001
Email
A.kazeminejad@mazums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available