Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the Effectiveness of Lawsonia Inermis Leaves Extract Ointment with Phenytoin Ointment on Post Operative Pilonidal Sinus Wound

Protocol summary

Study aim
Effect of Lawsonia Inermis Leaves extract on Post Operative Pilonidal Sinus Wound

Design
A controlled clinical trial with parallel, double-blind, randomized groups, phase 3 on 63 patients. A table of random numbers is used for randomization.

Settings and conduct
All pilonidal sinus patients undergoing surgery at Besat Hospital in Hamadan are eligible for inclusion in the study and will be divided into three groups, including the use of topical lawsonia inermis leaves ointment, topical phenytoin ointment, and Eucerin ointment. Standard saline treatment for all three groups was also performed on a daily basis. The method of treatment allocation is simple random sampling. How to get blind is double-blind.

Participants/Inclusion and exclusion criteria
Entry requirements : Age 10 to 70 years, BMI less than 35. Exit conditions : History of allergy to the compounds in Lawsonia Inermis; underlying diabetes mellitus, cancer and immune system deficiency, radiotherapy or chemotherapy

Intervention groups
1. In the first group, after surgery, a lawsonia inermis leaves extract is used at the base of Eucerin for wound healing. In the second group, after surgery, topical phenytoin ointment is used for wound healing. 3. In the third group, after surgery, Eucerin is used.

Main outcome variables
Wound erythema; Wound discharge; Wound length; Wound depth; Wound volume; Wound healing time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200125046248N1**
Registration date: **2022-05-26, 1401/03/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-26, 1401/03/05**
Update count: **0**

Registration date
2022-05-26, 1401/03/05

Registrant information

Name
Seyed Arsalan Khosravi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2220 4623

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Lawsonia Inermis Leaves Extract Ointment with Phenytoin Ointment on

Post Operative Pilonidal Sinus Wound

Public title
The Effect of Lawsonia Inermis Leaves extract on Wound Healing
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 10 to 70 years BMI < 35
Exclusion criteria:
History of allergy to the compounds in Lawsonia Inermis
Underlying diabetes, cancer, and immune deficiency
History of radiotherapy and chemotherapy
Age
From **10 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **63**
Randomization (investigator's opinion)
Randomized
Randomization description
in this study, simple randomization is performed using a table of random numbers. To use the table, first the method of reading the table numbers is determined and then the numbers are intended for study groups and is recorded . for example, even numbers are considered for intervention A and odd numbers are considered for intervention B. These sequences are created using spss software and studied based on them .
Blinding (investigator's opinion)
Double blinded
Blinding description
All three drugs are the same in shape, color, odor and method of use and are indistinguishable from the researcher, examiner, participating patients and data analyzer. Each drug has a code with which it is executed and the data with the codes are entered in the table and presented to the analyzer. Finally, after performing the analysis, the codes will be opened.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahed University of Medical Sciences
Street address
No 1, Disharieh Alley, Shahid Darbandi Ave, Tajrish, Tehran Town
City
Tehran
Province
Tehran
Postal code
1963953313
Approval date
2020-01-25, 1398/11/05
Ethics committee reference number
IR.SHAHED.REC.1398.116

Health conditions studied

1

Description of health condition studied
Wound; Surgical wounds
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Wound erythema
Timepoint
Wound examination for wound erythema 7, 14 and 28 days after starting topical ointment
Method of measurement
Visual examination

2

Description
Discharge from wound
Timepoint
Wound examination to evaluate any discharge 7, 14 and 28 days after starting topical ointment
Method of measurement
Visual examination

3

Description
Wound length
Timepoint
Wound length measurement 7, 14 and 28 days after starting topical ointment
Method of measurement
Caliper device

4

Description
Wound Depth
Timepoint
Wound depth measurement 7, 14 and 28 days after starting topical ointment
Method of measurement
Caliper device

5

Description
Wound volume
Timepoint
7, 14 and 28 days after starting topical ointment
Method of measurement
Complete wound filling with normal saline to measure wound volume with Syringe

6

Description
Wound healing time
Timepoint
7, 14 and 28 days after starting topical ointment.
Method of measurement
Wound examination to determine the time of complete wound healing

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One percent ointment containing aqueous extract of Lawsonia Inermise leaves at the base of Eucerin, which is coated topically twice a day for one month whole wound after pilonidal sinus surgery.
Category
Treatment - Drugs

2

Description
Intervention group: Phenytoin ointment 1% Daruopaksh Company, which is coated topically twice a day for one month whole wound after pilonidal sinus surgery.
Category
Treatment - Drugs

3

Description
Control group: Eucerin ointment which is coated topically twice a day for one month whole wound after pilonidal sinus surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Mohammad Reza Javadi
Street address
Best Hospital, Hokama Ave, Shahid Motahari Blv, Hamadan Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Zahra KiaSalari
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahed University
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
Shahed University

Full name of responsible person
Seyed Arsalan Khosravi

Position
Phd of Iranian Traditional Medicine

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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hasan namdar

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associate professor

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Other areas of specialty/work
Traditional Medicine

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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
The study is still undergoing .

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available