Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Topical Safflower (Carthamus tinctorius L.) Seed Oil on Open Wound Healing in Patients with Pilonidal Sinus Following Surgery: A Randomized Controlled Clinical TriaL

Protocol summary

Study aim

Determining the local effect of safflower seed oil (Carthamus tinctorius) on the healing process of open wounds in patients with pilonidal cysts after surgery

Design

A controlled, parallel-group, single-blind, randomized, phase 2 clinical trial on 60 patients. The sealedenvelop website will be used for randomization.

Settings and conduct

This study will be conducted in Yasuj, Iran. Eligible participants will be randomly allocated to the intervention and control groups using block randomization. The intervention group will receive topical safflower seed oil, while the control group will receive standard wound care. Wound healing will be assessed weekly. Outcome assessor blinding will be implemented, with the assessor remaining unaware of participants' group allocation.

Participants/Inclusion and exclusion criteria

Major inclusion criteria: Definite diagnosis of pilonidal disease by a surgeon and open excision surgery Absence of clinical signs of active wound infection at the time of study entry Major exclusion criteria: Diabetes Vascular disorders

Intervention groups

The intervention group will be given safflower oil, which will be applied daily to the area of the wound, using a fingernail-sized amount, after washing the wound with ordinary gauze, and then applied to the wound and bandaged. The control group will receive standard treatment, including washing and dressing with ordinary gauze daily. The intervention period is 4 weeks.

Main outcome variables

Wound healing time; pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260630070020N1**
Registration date: **2026-07-09, 1405/04/18**
Registration timing: **prospective**

Last update: **2026-07-09, 1405/04/18**
Update count: **0**

Registration date

2026-07-09, 1405/04/18

Registrant information

Name

Ali Keshvari khanimeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7005

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-06, 1405/05/15

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Topical Safflower (Carthamus tinctorius L.) Seed Oil on Open Wound Healing in Patients with Pilonidal Sinus Following Surgery: A Randomized Controlled Clinical TriaL

Public title
Effect of Safflower Oil on Postoperative Wounds Following Pilonidal Cyst Surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of pilonidal disease by a surgeon and open excision surgery Absence of clinical signs of active wound infection at the time of study entry

Exclusion criteria:
Having diabetes History of clotting disorders or deep vein thrombosis

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants in this study will be allocated to the intervention and control groups using **block randomization** with **individual randomization** as the unit of randomization. To ensure balanced group sizes and reduce the predictability of treatment allocation, **random blocks of variable sizes (2, 4, 6, and 8)** will be used. **Stratified randomization** will not be applied. The random allocation sequence will be generated using the **Sealed Envelope** website, and participants will be assigned to either the intervention group (A) or the control group (B) according to the generated sequence. To ensure **allocation concealment**, the randomization sequence will be maintained by an independent third party, and a unique study code will be assigned to each participant before enrollment, ensuring that the researcher remains unaware of the participant's treatment allocation until the time of assignment.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, patient blinding will not be performed. Because the comparison will be made with the standard treatment, which only includes washing and dressing, and the use of ointment has no place in the standard treatment. However, the blinding of the evaluator will be performed. In this way, the patients will be fully aware in advance that they will not provide the evaluator with information about their treatment during periodic assessments, and the evaluator will not ask about the type of treatment of the patients during periodic assessments. At the beginning of the study, the third party will provide each patient with a unique code, then record the information related to the patient's allocation to one of the study groups along with the unique code, and at the end of the study, after data collection, the recorded information will be made available to the researcher for data analysis.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences

Street address
Daneshgah St., Motahari Blvd., Jahad Town

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591875111

Approval date
2026-05-20, 1405/02/30

Ethics committee reference number
IR.YUMS.REC.1405.053

Health conditions studied

1

Description of health condition studied
Pilonidal cyst

ICD-10 code
L05

ICD-10 code description
Pilonidal cyst and sinus

Primary outcomes

1

Description
Pain intensity

Timepoint
Before and after the intervention

Method of measurement
Using a visual analog scale (VAS)

2

Description
Wound healing time
Timepoint
After the intervention
Method of measurement
Using the PUSH scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to standard treatment, patients will receive topical safflower seed oil (Carthamus tinctorius). After washing the wound daily, approximately a fingertip of the oil is placed on a gauze pad and applied to the wound bed, followed by a dressing. The dressing will be changed every 24 hours for the first week and every 48 hours from the second week onwards for a period of 4 weeks.
Category
Treatment - Other

2

Description
Control group: Patients will receive standard wound care, which includes daily irrigation of the wound with normal saline and dressing with plain sterile gauze, without the use of safflower seed oil or other topical products. The dressing will be changed every 24 hours for the first week and every 48 hours from the second week onwards for a period of 4 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Jalil Hospital
Full name of responsible person
Masoumeh Alizadeh
Street address
Imam reza St., Gharani Blvd., Imim Hossein Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
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Daneshgah St., Motahari Blvd., Jahad Town
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research@yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Ali Keshvari Khanimeni
Position
Resident
Latest degree
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Other areas of specialty/work
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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
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
After the completion of the study, all study data will be shared after being de-identified
When the data will become available and for how long
One month after the completion of the intervention, the data of the main variables of the study will be shared
To whom data/document is available
After The Publication Of The Article, all individuals will have access to its content
Under which criteria data/document could be used
Individuals associated with the medical and therapeutic fields may utilize the data from this study to conduct new research
From where data/document is obtainable
Via official email to the corresponding author at: r_hosseinpour@yahoo.com.
What processes are involved for a request to access data/document
The applicant must submit their formal request via the organization's email to the responsible author's email address. The accountable author will provide the information to the applicant within a maximum of 2 weeks after the applicant confirms the information.
Comments