

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of Teucrium Polium extract ointment in open wound healing of pilonidal sinus surgery

Protocol summary

Study aim

This study aims to determine the effect of Teucrium Polium ointment on open wound healing of the Pilonidal sinus area.

Design

The study is a double blind, phase three, randomized study on 132 patients with intervention, control and placebo groups, in such a way that the cards containing letters A,B,C are thrown in a container; card A for the intervention group, card B for the control group and card C is for the placebo group.

Settings and conduct

The Study population are the patients referred to Shahid Beheshti Hospital in Yasouj who will undergo open pilonidal sinus surgery which is divided into three groups: intervention (treatment with Teucrium Polium), control (treatment with normal saline), placebo (treatment with Osirin). The study is done double blind for the researcher and analyzer. After surgery, wounds of all three groups are washed with normal saline for up to a week, and then the considered dressing (Teucrium Polium, Osirine) is applied to the wound daily, and all groups are observed and records the healing process of the wound weekly for up to two months with Seeing their doctor. The next visit and review in terms of recurrence will be three months later. Data analysis will be done using statistical tests.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 45 years, skin defect after open Pilonidal sinus surgery with size of 5-10cm, having a gluteal infection; exclusion criteria: Diabetes, cardiac and kidney diseases, immunodeficiency, history of chemotherapy, abnormal bleeding from the wound site, drug allergy.

Intervention groups

First intervention group had Teucrium polium bandage, second group (control group) normal saline dressing, and the third group (placebo) had dressing with osirin.

Main outcome variables

Pilonidal sinus ulcer healing following open surgery;
Pilonidal sinus ulcer Infection following open surgery;
Recurrence of Pilonidal sinus.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200520047522N1**

Registration date: **2021-09-20, 1400/06/29**

Registration timing: **retrospective**

Last update: **2021-09-20, 1400/06/29**

Update count: **0**

Registration date

2021-09-20, 1400/06/29

Registrant information

Name

Seyed nooradin Hossini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 1813

Email address

nooradin.hosseini@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Teucrium Polium extract ointment in open wound healing of pilonidal sinus surgery

Public title
Evaluation of the effect of Teucrium Polium extract ointment in open wound healing of pilonidal sinus surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All patients who underwent Pilonidal sinus surgery Disuse of drugs affecting wound healing Having a gluteal area infection
Exclusion criteria:
 Chronic systemic disease (Kidney failure, Diabetes, Rheumatism, Immunodeficiency disease) Abnormal bleeding from the wound site Patients treated with Immunosuppressive drugs like Corticosteroids Drug allergy

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **132**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted block randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
All samples are given a card with the group code and the date of re-referral in order to remind the patient and the contact number of the registered researcher, neither the researcher nor the surgeon is aware of how the samples are in the three groups.

Placebo
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

Shahid Beheshti Hospital, Shahid Montazari St., Yasuj

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591794857

Approval date

2020-03-07, 1398/12/17

Ethics committee reference number

960581

Health conditions studied

1

Description of health condition studied

Pilonidal sinus

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Healing of a Pilonidal sinus ulcer following open surgery

Timepoint

Before the intervention and one, two, three, four, five, six, seven, eight weeks and 6 months after the starting consumption of Teucrium Polium ointment.

Method of measurement

Evaluation by the surgeon

Secondary outcomes

1

Description

Side effects (Allergy)

Timepoint

At all stages of project implementation

Method of measurement

As a regular visit and examination and recording the patient's complaints

Intervention groups

1

Description

The first intervention group: Dressing with Teucrium

polium.To prepare the ointment, the plant is dried according to standards and extracted with 70% ethanol and then evaporates in a rotary apparatus at 40° C and incubated at 37°C to dry extract and the extract is dissolved in distilled water. And then prepared at the base of osirine 10%.For two months the ointment will be applied daily after washing the wound, and then every seven or eight week until six months,it is evaluated in person by a doctor.

Category

Treatment - Drugs

2

Description

Second Intervention group: dressing with Osirin, which is prepared in the form of Osirine 10% by a pharmacist and it will be applied to the wound daily For two months and then and every seven to eight week until six months ,it is evaluated in person by a doctor.

Category

Treatment - Drugs

3

Description

Control group:Normal siline lovage. The wound is washed daily with Normal saline solution for up to two months and evaluated in person by a doctor every seven to eight week until six month in person by a doctor.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Shahid Montazari St., Yasuj

Full name of responsible person

Seyed nooradin Hosseini

Street address

Yasuj, Beheshti Hospital of Yasuj

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nooradin.hoseini@yums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Dr.Hossein Mari Oryad

Street address

Yasuj University of Medical Sciences,Yasuj

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oryad.hossein@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

Seyed nooradin Hosseini

Position

Associate

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

Name of organization / entity

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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