

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of the effect of ZOUSH natural ointment on open wound healing due to surgery in patients with pilonidal sinus

Protocol summary

Study aim

Evaluation of the effect of ZOUSH natural ointment on open wound healing due to surgery in patients with pilonidal sinus

Design

Clinical trial has two groups of control and drug; 70 people who are eligible to enter the study will be selected.

Settings and conduct

Patients are compared in two groups: During surgery, wound volume is measured by filling normal saline with a graduated syringe; The ointment is applied in such a way that the day after the surgery, the wound site is first washed with water and baby shampoo, then the wound surface is completely covered with a layer of ointment and a dressing is applied. This process is continued once every 24 hours until the formation of granulation tissue, and wound healing is followed by examination and photography until it reaches the stage of tissue formation and epithelialization. In the group without ointment, only water washing and baby shampoo and wound dressing without any effective substance is used. Patients in both groups are followed up at intervals of 7 days, 14 days, one month, and three months after surgery, and the results are recorded.

Participants/Inclusion and exclusion criteria

Patients with primary pilonidal sinus who have undergone open surgery; Males under 45 years; BMI of less than 35

Intervention groups

A group of 70 patients with pilonidal sinus surgery who underwent open surgery

Main outcome variables

If Zouch herbal ointment accelerates wound healing and has no specific side effects, in the next stage, a clinical study will be performed on patients with more complex wounds.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201106049283N1**

Registration date: **2021-01-13, 1399/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-13, 1399/10/24**

Update count: **0**

Registration date

2021-01-13, 1399/10/24

Registrant information

Name

Mahdi Mesgaranzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 3582

Email address

mahdimesgaran@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of ZOUSH natural ointment on open wound healing due to surgery in patients with pilonidal sinus

Public title

Evaluation of the effect of ZOUSH natural ointment on open wound healing due to surgery in patients with pilonidal sinus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with primary pilonidal sinus who have undergone open surgery BMI less than 35 Conscious consent to participate in the project Males under 45 years

Exclusion criteria:

Accompanying metabolic disorders including diabetes and uremic disorders Receive immunosuppressive drugs

Age

From **15 years** old to **45 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups using statistical software and Permuted block randomization (With 4 and 6 numbers blocks), The vital statistician arranges random groups and puts each random situation in an envelope, When each patient enters the study, an envelope is opened and his treatment group is identified.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Mollasadra street

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-10-31, 1399/08/10

Ethics committee reference number

IR.BMSU.BAQ.REC.1399,041

Health conditions studied

1

Description of health condition studied

Wounds from pilonidal sinus surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

This clinical trial study will be performed to evaluate the restorative effect of ZOUSH on wounds caused by pilonidal sinus surgery in 70 patients referred to Baqiyatallah Hospital.

Timepoint

Intervals 7 days, 14 days, and one month and three months after surgery

Method of measurement

During surgery after establishing dimensional homeostasis; the wound volume is measured by filling normal saline with a graduated syringe.

2

Description

The size of the wound

Timepoint

Study days 7, 14, 30 and 90

Method of measurement

BATES JENSIN Wound Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To prepare Zoush herbal ointment, Zataria multiflora Boiss and Origanum vulgare plants is purchased from Barij Essence Herbal Medicine Center and the alcoholic extract is prepared, and finally the extracts are delivered in powder form from the same company. The composition of the extracts is measured using gas chromatography. The extracts dissolve 1/3 in dimethyl sulfoxide. Honey is dissolved in a 1/3 ratio in

sterile distilled water. Polyurethane in a ratio of 1/3 is first dissolved in 6 M urea and then placed on indirect heat to evaporate the urea. Plant extracts, Zataria multiflora, and Origanum vulgare soluble in DMSO, water-soluble honey, and urea-soluble polyurethane are mixed one by one in a separate falcon and will be used as the initial stock of Zoush ointment in other stages.

Category

Treatment - Drugs

2**Description**

Control group: Only water washing and baby shampoo are used without any effective ingredients.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Baqiyatallah Hospital

Full name of responsible person

mahdi mesgaranzade

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Mollasadra Ave.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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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

Bagheiat-allah 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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mahdi Mesgaranzade

Position

Non-faculty specialist physician

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Full name of responsible person

Mahdi Mesgaranzade

Position

Non-faculty specialist physician

Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not 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

The research data will eventually be published in an English paper.

When the data will become available and for how long

Information will be available endlessly from the end of the study.

To whom data/document is available

everyone

Under which criteria data/document could be used

In order to spread information about the treatment of burn patients, the results of the study will be made available to those interested.

From where data/document is obtainable

Journal database

What processes are involved for a request to access data/document

by E-mail, which will eventually be answered within a month.

Comments