Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Street address

Mollasadra Ave.

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8126 3582

Email

mahdimesgaran@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mahdi Mesgaranzade

Street address

Mollasadra

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8126 3582

Email

mahdimesgaran@yahoo.com

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

Street address

Mollasadra

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8126 3582

Email

mahdimesgaran@yahoo.com

Person responsible for scientific 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

Street address

Mollasadra

City

Tehran

Province
Tehran
Postal code
1435916471
Phone
+98 21 8126 3582
Email
mahdimesgaran@yahoo.com

Person responsible for updating data

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
Street address
Mollasadra
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8126 3582
Email
mahdimesgaran@yahoo.com

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