Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Arnebia euchroma ointment on postoperative pain burning and wound healing in hemorrhoidectomy patients

Protocol summary

Study aim
Determining the effect of Arnebia euchroma ointment, burning and healing wounds of patients' after hemorrhoidectomy, referring to Ghaem Shahr Hospital in Mashhad in 2019_2020

Design
Clinical trial with control and intervention group, with parallel, two-way, blind, randomized group, 120 patients. The blocks are then randomly selected using a random number table of up to 30 four blocks, which is continuously determined to determine the type of intervention (Pomadia control) to determine the patient's input number

Settings and conduct
This research is carried out in the operating room of Ghaem Hospital in Mashhad. The researcher was present in the patient's ward and after self-diagnosis and gaining conscious satisfaction and emphasis on confidentiality of information and checking the criteria for entering this research, the questionnaire will be sent to the patient and tested. 4, 12, 24) and 48, 4 and 7 days later. Also, report the amount of pain during the first defecation after surgery.

Participants/Inclusion and exclusion criteria
Criteria for admission include: 1_60 years_20 years, 2_don't have a history of anorectal surgery, inflammatory bowel disease, polyps and colorectal cancer3_ have hemorrhoids grade III and IV 4_ no history of oral NSAIDs, no history of alcoholism and alcoholism Outcome criteria: Pregnancy, the need for reoperation or dissatisfaction to continue treatment.

Intervention groups
After the surgery, two grams of the ointment Abu Khalsa's applied to the area of the operation and dressin AND This work is done by the applicants for 12 hours to a week. When the patient is hospitalized, the patient is guided by the patient.The control group received only two grams of ointment and dosing according to the intervention group for patients.

Main outcome variables
pain؛burning؛wound healing

General information

Reason for update
Acronym
Arnebia euchroma
IRCT registration information
IRCT registration number: **IRCT20200427047226N1**
Registration date: **2020-07-01, 1399/04/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-01, 1399/04/11**
Update count: **0**
Registration date
2020-07-01, 1399/04/11

Registrant information
Name
ehsan memarbashi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 56 3272 4978
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ehsan.memar1991@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-06-21, 1399/04/01
Expected recruitment end date
2020-09-22, 1399/07/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Arnebia euchroma ointment on postoperative pain burning and wound healing in hemorrhoidectomy patients

Public title

The effect of Arnebia euchroma ointment on postoperative pain burning and wound healing in hemorrhoidectomy patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

People with grade 3 and 4 internal hemorrhoids Be at least 20 years old and at most 60 years old

Exclusion criteria:

Lack of heart, liver and kidney disease No history of alcohol or drug abuse No history of colorectal surgery

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups of tests and controls. Patient allocation in two intervention groups and control group using Block randomization method and in 16 possible four-block blocks that are regulated in each block of two letters AA, ie Arnebia euchroma intervention and CC letter, ie control. The blocks are then randomly selected using a table of random numbers up to 30 four-block blocks, which are continuously determined to determine the type of intervention (ointment or control) to determine the patient's input number.

Blinding (investigator's opinion)

Double blinded

Blinding description

the type of intervention inside the envelope and the intervention number on it. 120 envelopes are registered so that a 30 gram medicine tube can be placed inside it, which can be used twice a day for up to a week.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

39/5000 Teacher Street. Moallem Square Research Deputy

City

sary

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2020-04-25, 1399/02/06

Ethics committee reference number

IR.MAZUMS.REC.1399.111

Health conditions studied

1

Description of health condition studied

Hemorrhoidectomy

ICD-10 code

K62

ICD-10 code description

Other diseases of anus and rectum

Primary outcomes

1

Description

PAIN

Timepoint

After surgery (recovery), 4, 12 and 24 hours after surgery_2 and 4 and 7 days after surgery

Method of measurement

Visual Analogue Scale

2

Description

burning

Timepoint

After surgery (recovery), 4, 12 and 24 hours after surgery_2 and 4 and 7 days after surgery

Method of measurement

Visual Analogue Scale

3

Description

wound healing
Timepoint
One week after surgery
Method of measurement
Grade 1 and 2 poor repair, 3 and 4 good repair5 excellent repairs

Secondary outcomes

1

Description
Vomit
Timepoint
Duration of hospitalization
Method of measurement
The number of times

2

Description
Nausea
Timepoint
Duration of hospitalization
Method of measurement
The number of times

3

Description
Feeling unwell in the stomach
Timepoint
Duration of hospitalization
Method of measurement
The number of times

4

Description
Diarrhea
Timepoint
Duration of hospitalization
Method of measurement
The number of times

5

Description
Defecation
Timepoint
Duration of hospitalization
Method of measurement
The number of times

6

Description
Urine
Timepoint
Duration of hospitalization
Method of measurement
The number of times

7

Description
Received housing
Timepoint
Duration of hospitalization
Method of measurement
Type and volume of medication

8

Description
Headache
Timepoint
Duration of hospitalization
Method of measurement
yes_no

9

Description
Fear of first defecation
Timepoint
During defecationمعیار آنالوگ بینایی
Method of measurement
(Visual Analogue Scale)

10

Description
Itching
Timepoint
Duration of hospitalization
Method of measurement
(Visual Analogue Scale)

Intervention groups

1

Description
Intervention group: ARNEBIA Arnebia euchroma plants and roots were purchased from the Sari plant market in northern Iran in February 2017. This plant was kept in the Faculty of Pharmacy, Mazandaran University of Medical Sciences. A. euchroma root was washed and dried in a preheated oven at 40 درجه C for 8 hours. This ointment is made according to the formula of traditional Iranian medicine. Arnebia euchroma ointment is made up of 10% components (10 g of A. euchroma roots, 20 g of goat fat, 15 g of beef butter, 20 g of glycerin and 35 g of Osirine. The weight ratio of Arnebia euchroma ointment was 10% of the original weight. A. euchroma was eaten in a container and heated with beef butter, goat fat and glycerin at 150-100 برای C for 30 minutes, then the samples were placed inside the autoclave for 18 minutes at 121 اد C. The sample was mixed with Osirine, 0.025 g of methyl paraben and 0.015 g of propylene parabens and rubbed for 5 minutes to form a homogeneous ointment. This product was filled in sterile tubes of 50 g and in Was put clean environment. In order to evaluate the stability and concentration ointment formulations them for 2 weeks at 4, 25 and 40 ° C were

maintained.After the surgery, the surgeon rubs and bandages two grams of the ointment arnebia in the area of the operation with gas, and this is done every 12 hours to a week by the applicator. As long as the patient is hospitalized, the patient will be guided by the facilitator, and all patients will be instructed on how to do the same twice a day at home and after discharge.

Category

Treatment - Drugs

2

Description

Control group: ousirin .After the surgery, the surgeon rubs and bandages two grams of the ointment ousirin in the area of the operation with gas, and this is done every 12 hours to a week by the applicator. As long as the patient is hospitalized, the patient will be guided by the facilitator, and all patients will be instructed on how to do the same twice a day at home and after discharge.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ismail Saburi

Full name of responsible person
EHSAN MEMARBASHI

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mazandaran University of Medical Sciences

Proportion provided by this source
70

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
Mazandaran University of Medical Sciences

Full name of responsible person
memarbashi

Position
surgical technologist

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
There is no further information
Study Protocol
No - There is not 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
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
In this study, confidential data information of individuals, which are provided from the people present in the study without name and specifications for better presentation of the article
When the data will become available and for how long
Until this article is published
To whom data/document is available
People who are involved in this study.
Under which criteria data/document could be used
To analyze data to achieve P Value
From where data/document is obtainable
To study colleagues and journals
What processes are involved for a request to access data/document
the results of the research can be sent by email to the applicants.
Comments