

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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)

##### Phone

+98 56 3272 4978

##### Email address

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 defecation معیار 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 °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 °C for 30 minutes, then the samples were placed inside the autoclave for 18 minutes at 121 °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

##### Street address

Ghaem Hospital, Ahmadabad St.

##### City

MASHHAD

##### Province

Razavi Khorasan

##### Postal code

99199-91766

##### Phone

+98 56 3272 4978

##### Email

EHSAN.MEMAR1991@GMAIL.COM

### Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Ebrahim Nasiri Fermi

##### Street address

Sari, 18 km of Khazarabad Road, Prophet's University Complex (PBUH)

##### City

sary

##### Province

Mazandaran

##### Postal code

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##### Phone

+98 56 3272 4978

##### Email

ebrahim.Nasiri.f@gmail.com

#### 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

##### Street address

North Besat 4 pelak 31

##### City

ferdows

##### Province

South Khorasan

##### Postal code

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##### Phone

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##### Email

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### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Ebrahim Nasiri Fermi

##### Position

Faculty of Mazandaran University of Medical Sciences

##### Latest degree

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

103/5000 Sari, Imam Square, Joibar Three Ways, at the beginning of Valiasr Highway, Central Headquarters of Mazandaran University of Medical Sciences

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**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

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**Position**

surgical technologist

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Province**

South Khorasan

**Postal code**

9771815917

**Phone**

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ehsan.memar1991@gmail.com

**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**