

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Evaluation of the efficacy and safety of an innovative flavonoid lotion in patients with hemorrhoid; A Randomized Clinical Trial

#### Protocol summary

##### Study aim

In this study we aimed to produce a combination of olive oil and honey propolis in the form of lotions and assess its healing and side effects in comparison with routine treatment, anti-hemorrhoid ointment (containing hydrocortisone and lidocaine).

##### Design

Randomized controlled clinical trial, not blinded, phase 2-3 on 100 patients. Excel software permutations formula was used to randomize the block sequences.

##### Settings and conduct

100 over 18 years patients, with second-degree hemorrhoids or above, who are referred to the colonoscopy ward of Baqiyatallah hospital will be included in the study. Patients in both groups will use the dosage of medication similarly (topical/rectal, twice daily for one month).

##### Participants/Inclusion and exclusion criteria

Inclusion: Patients with grade 2 or more hemorrhoid degree, diagnosed by colonoscopy. exclusion: Patients with inflammatory bowel disease, pregnancy, lactation, history of hemorrhoid surgery and other anorectal diseases such as anal fissures, anorectal malignancies, heavy bleeding, general instability, hemorrhoid complications or exacerbation of symptoms (such as bleeding and pain) and occurrence of drugs side effects are excluded from the study.

##### Intervention groups

The case group is treated with flavonoid lotion and the control group treated with anti-hemorrhoid ointment, twice daily for one month. Patients are followed weekly with history and physical examination

##### Main outcome variables

Therapeutic effect of flavonoid leucine The safety of the flavonoid leucine Comparison of flavonoid leucine function with anti-hemorrhoid ointment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210325050769N2**

Registration date: **2021-12-27, 1400/10/06**

Registration timing: **retrospective**

Last update: **2021-12-27, 1400/10/06**

Update count: **0**

##### Registration date

2021-12-27, 1400/10/06

##### Registrant information

##### Name

Mohammad Heiat

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8126 2072

##### Email address

mohamad.heiat@bmsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2021-02-19, 1399/12/01

##### Actual recruitment start date

2020-04-20, 1399/02/01

##### Actual recruitment end date

2020-04-29, 1399/02/10

##### Trial completion date

2021-06-05, 1400/03/15

##### Scientific title

Evaluation of the efficacy and safety of an innovative flavonoid lotion in patients with hemorrhoid; A Randomized Clinical Trial

## Public title

Evaluation of the effectiveness of flavonoid lotion in the treatment of hemorrhoids

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with grade 2 or higher hemorrhoids Age range 18-75 Lack of drug allergy to lotion Lack of confounding underlying disease such as diabetes Patient satisfaction

### Exclusion criteria:

Patient dissatisfaction Higher or lower grades of disease Presence of drug allergy to plant Lotion Existence of confounding underlying disease such as diabetes

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

Actual sample size reached: **86**

## Randomization (investigator's opinion)

Randomized

## Randomization description

To randomize the study, the block method is used with individual randomization unit and Excel software (to generate random block sequences). The printed blocks will be placed in a sealed envelope and the researcher will randomly pick up one of them and assign the patients to the intervention or control group.

## 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

Research Ethics Committees of Baqiyatallah Hospital

##### Street address

Vanak sq, Mollasadra street, Southern sheikhbahaei street

##### City

Tehran

##### Province

Tehran

##### Postal code

1435915371

##### Approval date

2020-02-18, 1398/11/29

##### Ethics committee reference number

IR.BMSU.BAQ.REC.1398.032

## Health conditions studied

### 1

#### Description of health condition studied

Hemorrhoids

#### ICD-10 code

K64

#### ICD-10 code description

Hemorrhoids and perianal venous thrombosis

## Primary outcomes

### 1

#### Description

Hemorrhoid grade

#### Timepoint

weekly

#### Method of measurement

With history and physical examination

### 2

#### Description

Rectal bleeding

#### Timepoint

Weekly

#### Method of measurement

With history and physical examination

### 3

#### Description

Anal pain

#### Timepoint

Weekly

#### Method of measurement

With history and physical examination

### 4

#### Description

Incomplete defecation

#### Timepoint

Weekly

#### Method of measurement

With history and physical examination

### 5

#### Description

Anal irritation

**Timepoint**

Weekly

**Method of measurement**

With history and physical examination

**6**

**Description**

Anal discharge

**Timepoint**

weekly

**Method of measurement**

With history and physical examination

**7**

**Description**

Anal discomfort

**Timepoint**

Weekly

**Method of measurement**

With history and physical examination

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Patients in this groups use the herbal lotion topically/rectal, twice a day for one month. Each 100 mg of produced flavonoid lotion has 70% flavonoid content (1/2 honey propolis, 1/2 olive oil) and 30% Excipient as underlying solvent.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Patients in this groups use the anti-hemorrhoid ointment topically/rectal, twice a day for one month. Iran Najo anti-hemorrhoid ointment is available routinely in pharmacies and each 100 grams of it contains hydrocortisone acetate (0.275 grams), lidocaine (5 grams), aluminum subacetate (3.5 grams) and zinc oxide (18 grams).

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Baqiyatallah Hospital

**Full name of responsible person**

Sara Razdar

**Street address**

Vanak sq, Mollasadra street, Southern sheikhbahaei street

**City**

Tehran

**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 21 8861 2072

**Email**

Srazdar@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Hossein Khedmat

**Street address**

Vanak sq, Mollasadra street, Southern sheikhbahaei street

**City**

Tehran

**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 21 8861 2072

**Email**

dr.khedmat@gmail.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**

Sara Razdar

**Position**

Gastroenterologist and liver specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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Srazdar@gmail.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Sara Razdar

**Position**

Gastroenterologist and liver specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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**Email**

Srazdar@gmail.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Mohammad Heiat

**Position**

Research Manager of Baqiyatallah Research Center for Gastroenterology and Hepatology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Internal Medicine

**Street address**

Vanak sq, Mollasadra street, Southern sheikhbahaei street

**City**

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**Province**

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**Postal code**

1435915371

**Phone**

+98 21 8861 2072

**Email**

Mohamad.heiat@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Undecided - It is not yet known if there will be 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**

All data can be shared after un-identification of individuals

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

The data will be available to researchers working in academic centers as well as to industry professionals

**Under which criteria data/document could be used**

Statistical analyzes on data are allowed for scientific and research use after obtaining permission from the project manager

**From where data/document is obtainable**

For data and documentation, refer to the Research Center for Gastroenterology and Liver Diseases and Dr. Mohammad Heiat(Research Director of the Research Center)

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

After receiving a written request from researchers working in academic and scientific institutions as well as people working in industry by the Baqiyatallah Research Center for Gastroenterology and Liver Disease and reviewing the application in the Research Council of the Research Center, the documents or data files will be delivered to the applicant after about 10 days.

**Comments**