

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

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

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

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

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

Tehran

Province

Tehran

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