

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Efficacy of Adding Daflon to the Conventional Treatment on the Improvement of Symptoms and Health-Related Quality of Life in the Patients with Acute Hemorrhoids: A randomized clinical trial

Protocol summary

Study aim

The Efficacy of Adding Daflon to the Conventional Treatment on the Improvement of Symptoms and Health-Related Quality of Life in the Patients with Acute Hemorrhoids

Design

Randomized , parallel clinical trial study

Settings and conduct

Rasoul-e-Akram Hospital Patients with acute hemorrhoids selected in this study were treated with Daflon (500 mg) three tablets twice daily for the first four days and two pills twice daily for three days afterwards. Patients were followed up by SF-12V1 Health Survey questionnaire (telephone and face-to-face visits) before and after two weeks after treatment in terms of severity of pain and health examination.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The patients with age above 18 years and acute hemorrhoid crisis Exclusion criteria: The patients with a history of previous anorectal or hemorrhoid surgery, hemorrhoid grade I and IV, lactation, pregnancy, medications such as anti-depressant and flavonoid drugs, severe systemic disease, hypertension, seizure, non-cooperative, cancer, sleep disorders and allergy to daflon.

Intervention groups

Group A; Anti-hemorrhoidal ointment, Seitz bath, and lifestyle modification. Group B; received three tablets of daflon(500 mg) 1500 mg bid for the first four days and after that two tablets of daflon 1000 mg bid for next three days plus conventional treatment same as the group A.

Main outcome variables

Anal pain score; Bleeding status; SF-12V1 Health Survey Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141201020178N9**

Registration date: **2019-05-24, 1398/03/03**

Registration timing: **retrospective**

Last update: **2019-05-24, 1398/03/03**

Update count: **0**

Registration date

2019-05-24, 1398/03/03

Registrant information

Name

Marjan Mokhtare

Name of organization / entity

Iran University of Medical sciences,Rasoul Akram Hospital,Colorectal Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 6652 2845

Email address

mokhtare.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-16, 1396/12/25

Expected recruitment end date

2019-01-19, 1397/10/29

Actual recruitment start date

2018-04-04, 1397/01/15

Actual recruitment end date

2019-01-20, 1397/10/30

Trial completion date

2019-02-04, 1397/11/15

Scientific title

The Efficacy of Adding Daflon to the Conventional Treatment on the Improvement of Symptoms and Health-Related Quality of Life in the Patients with Acute Hemorrhoids: A randomized clinical trial

Public title

estimation of the efficacy and adverse effect of daflon when it is added to the conventional treatments in patients with acute hemorrhoids

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age more than 18 years acute hemorrhoid crisis (anal pain and anal bleeding)

Exclusion criteria:

Grade I and IV of hemorrhoid previous history of surgery related to the anorectal or hemorrhoid disease lactation Patients with the history of other chronic systemic diseases, such as heart, kidney, or liver disease, hypertension, seizure pregnancy cancer history medications such as anti-depressant and flavonoid drugs non-cooperative sleep disorders allergy to daflon

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **47**

Randomization (investigator's opinion)

Randomized

Randomization description

individual random table of random numbers generated by the computer softwares

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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, West Shahid Hemmat Highway, Intersection of Chamran and Sheikh Fazlollah Noori

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-08-23, 1397/06/01

Ethics committee reference number

IR.IUMS.FMD.REC.1397.246

Health conditions studied**1****Description of health condition studied**

Acute Hemorrhoidal disease

ICD-10 code

K64

ICD-10 code description

Hemorrhoids and perianal venous thrombosis

Primary outcomes**1****Description**

pain score

Timepoint

Before and two weeks after starting treatment

Method of measurement

VAS

2**Description**

bleeding

Timepoint

Before and two weeks after starting treatment

Method of measurement

No bleeding / with every defecation / daily / weekly / monthly

3**Description**

SF-12V1 Health Survey Questionnaire

Timepoint

before and 2 weeks after the starting the treatment

Method of measurement

SF-12V1 questionnaire

Secondary outcomes

1

Description

Patient compliance rate

Timepoint

two weeks after starting treatment

Method of measurement

Data gathering sheet

2

Description

adverse effect rate

Timepoint

2 weeks after the beginning of the treatment

Method of measurement

patients data gathering sheets

Intervention groups

1

Description

Control group: topical anti-Hemorrhoid ointment, Sitz bath and lifestyle modifications

Category

Treatment - Drugs

2

Description

Intervention group; Daflon 1500 mg twice in a day orally in the first four days and 1000 mg twice in a day for three days later, added to the conventional treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Colorectal ResearchCenter ,Rasoul Akram Hospital

Full name of responsible person

Marjan Mokhtare

Street address

Niayesh Street, Sattarkhan Street

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Postal code

1445613131

Phone

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Email

marjanmokhtare@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Malakouti SK.

Street address

Hemat Highway next to Milad Tower, Iran University of Medical Sciences

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1449614535

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+98 21 86701

Email

info@iums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Marjan Mokhtare

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterologist and Hepatologist

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Person responsible for scientific inquiries

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be 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

IPD collected for the primary outcome measure only could be shared

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

This is only available for people working in academic institutions and/ or people working in businesses can also apply to receive it.

Under which criteria data/document could be used

People who working in academic institutions

From where data/document is obtainable

Corresponding author email addresses

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

Upto 3 months after approval of ID documents

Comments