Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 defication / 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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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
Gastroenteroogist and Hepatologist
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Person responsible for scientific inquiries

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Person responsible for updating data

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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