

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The evaluation of effects of Daflon tablet on symptoms of hemorrhoids, its relapse and patients' duration of hospitalization

Protocol summary

Study aim

The determination of effects of Daflon tablet on symptoms of hemorrhoids, its relapse and patients' duration of hospitalization

Design

Double-blinded, randomized, parallel clinical trial with a sample size of 200 patients; 100 patients in Daflon group and 100 patients in placebo group.

Settings and conduct

Participants are randomly selected from patients who are diagnosed by grade 3 or 4 of hemorrhoids in Shahid Madani surgery clinic in 2021 to 2022. After inclusion patients are allocated in to Daflon and placebo group. They will undergo treatment for 4 weeks. Eventually, patients are going to get assessed in terms of duration, severity and relapse of patients' signs and symptoms.

Participants/Inclusion and exclusion criteria

Patients over the age of 18 years old who were diagnosed with grade 3 or 4 of hemorrhoids based on a surgeons' physical exam and history taking are going to be included in the study. Patients who have history of previous treatment of hemorrhoids, consumption or allergy to Daflon tablet, renal failure or electrolytes imbalance, serious underlying disease, including immunodeficiency disease, hyperparathyroidism, complete heart block, addison's disease, intestinal disorders, or malignancies are going to get excluded from the study.

Intervention groups

Case group: 100 patients are going to receive Daflon 500mg tablet each 12 hours for 4 weeks. Control group: 100 patients are going to receive placebo each 12 hours for 4 weeks.

Main outcome variables

Duration of improvement in sign and symptoms; severity of symptoms; relapse of symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210625051698N1**

Registration date: **2021-07-06, 1400/04/15**

Registration timing: **prospective**

Last update: **2021-07-06, 1400/04/15**

Update count: **0**

Registration date

2021-07-06, 1400/04/15

Registrant information

Name

Mohsen Karimian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3255 8080

Email address

mohsenkarimian494@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-01-13, 1400/10/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of effects of Daflon tablet on symptoms of hemorrhoids, its relapse and patients' duration of hospitalization

Public title

The evaluation of effects of Daflon tablet on hemorrhoids

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients over the age of 18 years old who were diagnosed with grade 3 or 4 of hemorrhoids based on a surgeons' physical exam and history taking

Exclusion criteria:

Does not have a history of previous treatment of hemorrhoids. Does not have a history of consumption or allergy to Daflon tablet. Does not have a history of renal failure or electrolytes imbalance. Does not have a serious underlying disease, including immunodeficiency disease, hyperparathyroidism, complete heart block, Addison's disease, intestinal disorders, or malignancies.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated into the intervention and control groups using permuted balance block randomization. The blocks are four. Using STATA software, random numbers are generated from 1 to 6. Another number is generated when the previous number is more than 6, without considering it. An individual who is not participated in design and conduction of study prepares the random numbers and put them in pockets with a five-digit serial number. All pockets with 5 digit numbers open after including a patient, and the patient is allocated to one of the two groups. In the case group patients are given Daflon 500mg per 12 hours for 4 weeks. In contrast, the control group patients are given placebo per 12 hours for 4 weeks.

Blinding (investigator's opinion)

Double blinded

Blinding description

in this double blind study patients are not going to be aware of whether they have given placebo or Daflon. Moreover, the clinicians are not going to be aware of patients allocation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

Street address

Deputy of research, Alborz university of medical sciences, Safarian street, Golshahr

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2021-05-16, 1400/02/26

Ethics committee reference number

IR.ABZUMS.REC.1400.072

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**

Duration of improvements of sign and symptoms

Timepoint

4 weeks after inclusion

Method of measurement

Duration of times that takes for patients for their signs to get improved.

2**Description**

Severity of sign and symptoms

Timepoint

4 weeks after inclusion

Method of measurement

The severity of symptoms are going to get reported by patients 4 weeks after inclusion based on visual Analogue scale.

3

Description

Relapse of sign and symptoms

Timepoint

4 weeks after inclusion

Method of measurement

In case of resolution of symptoms in 4 weeks, patients report relapse of their symptoms.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Daflon group: After inclusion patients consume Daflon 500mg, which is produced Amin pharmaceutical company and comprise flavonoid agents by tablet each 12 hours (every day, twice a day) for 4 weeks (each participant consume 56 pills during the trial).

Category

Treatment - Drugs

2

Description

Control group: Placebo group: Patients consume placebo, which is similar to Daflon in terms of taste and appearance each 12 hours (every day, twice a day) for 4 weeks (each participant consume 56 pills during the trial).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani hospital

Full name of responsible person

Mohsen Karimian

Street address

Shahid madani hospital, Jahanshar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Noorisepehr

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Mohsen Karimian

Position

Residens

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable