

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating 5ASA efficacy in treatment of symptomatic hemorrhoid in non-IBD patients

Protocol summary

Study aim

Evaluating 5ASA efficacy in treatment of symptomatic hemorrhoid

Design

A randomized clinical trial with control group, with parallel groups, without blindness that, 100 patients randomly divided into two groups of 50 subjects with block sizes of 4.

Settings and conduct

The study population was patients over the age of 18 who referred to the Babol Spiritual Medical Center. Patients were randomly divided into two groups by computer-generated random number table method. Hemorrhoids and laxative treatment) plus 5-ASA suppository once daily for 2 weeks Control group: common hemorrhoid treatment (including anti-hemorrhoid ointment and laxative treatment) for 2 weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: Sigmoidoscopy, Hemorrhoids based on clinical indicators and examination Exclusion criteria: Hemorrhoids stage 3 and up, Ulcerative proctitis, Pregnancy or breastfeeding, Allergy to salicylates, Liver dysfunction and Renal dysfunction

Intervention groups

intervention group: Common hemorrhoid treatment (including anti-hemorrhoid ointment and laxative treatment) with 5-ASA suppository once a day for 2 weeks Control group: Common hemorrhoid treatment (including anti-hemorrhoid ointment and laxative treatment) for 2 weeks

Main outcome variables

Bleeding, Pain, Anal burning

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191226045897N2**

Registration date: **2021-05-03, 1400/02/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-03, 1400/02/13**

Update count: **0**

Registration date

2021-05-03, 1400/02/13

Registrant information

Name

Seyed Hassan Abedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8269

Email address

h.abedi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-29, 1400/02/09

Expected recruitment end date

2021-10-31, 1400/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating 5ASA efficacy in treatment of symptomatic hemorrhoid in non-IBD patients

Public title

Evaluating 5ASA efficacy in treatment of symptomatic

hemorrhoid

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Sigmoidoscopy Hemorrhoids based on clinical indicators and examination
Exclusion criteria:
Hemorrhoids stage 3 and up Ulcerative proctitis
Pregnancy or breastfeeding Allergy to salicylates Liver dysfunction Renal dysfunction

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients randomly divided into two groups of 50 subjects with 4 blocks and an allocation ratio of 1: 1. The free website WWW.randomization .com was used to generate the allocation sequence. The obtained sequence is written in separate sheets and placed in sealed envelopes and given to the main researcher for study.

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

The Ethics Committee of Babol University of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2020-09-26, 1399/07/05

Ethics committee reference number

IR.MUBABOL.REC.1399.306

Health conditions studied

1

Description of health condition studied

hemorrhoids

ICD-10 code

I84.9

ICD-10 code description

Unspecified haemorrhoids without complication

Primary outcomes

1

Description

Bleeding

Timepoint

Before intervention, 2 weeks after the initial intervention

Method of measurement

questionnaire

2

Description

Pain

Timepoint

Before intervention, 2 weeks after the initial intervention

Method of measurement

questionnaire

3

Description

Anal burning

Timepoint

Before intervention, 2 weeks after the initial intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Common hemorrhoid treatment (including anti-hemorrhoid ointment and laxative treatment) with 5-ASA suppository once a day for 2 weeks

Category

Treatment - Drugs

2

Description

Control group: Common hemorrhoid treatment (including anti-hemorrhoid ointment and laxative treatment) for 2 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

seyed Hassan Abedi

Street address

Ruhani Hospital, Daneshgah Square, Ganjafrroz Avenue

City

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47176-41367

Phone

+98 11 3233 8301

Email

h.abedi@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrroz Avenue

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rezaghadimi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Seyed Hassan Abedi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is still no plan for its publish

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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