

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

comparison of the effectiveness and patient tolerance of oral lavage of Rhamnus frangula extract and polyethylene glycol for colonoscopy preparation. A randomized controlled trial study

Protocol summary

Study aim

comparison of the effectiveness and patient tolerance of administration of Rhamnus frangula extract and polyethylene glycol in bowel preparation for colonoscopy

Design

This study is a randomized, double-blind clinical trial with parallel groups and a control group that will be performed with the participation of 116 patients ; Patients will be divided into intervention and control groups by block randomization

Settings and conduct

The samples will be selected from patients referred to the gastroenterology clinics of Emam Reza hospital of Tabriz .patients will be placed in one of the two groups receiving the Pidrolox and Rhamnus frangula extract sachetes. The Pidrolox group will prepare 4 packets of Pidrolox consuming 24 hours before the colonoscopy. The Rhamnus frangula group will also take 2 grams of Rhamnus frangula in 4 sachets .bowel preparation will be assessed by BOSTON score.researchers and patients and data analyzer will be blind in this study.

Participants/Inclusion and exclusion criteria

patients will be selected from the person referred to Gastroenterology clinics for colonoscopic evaluation, Inclusion criteria include: Age at 18-75 year, and willingness to participate,exclusion criteria also include:history of drug reaction, having dysphagia;swallowing disorders;ileus ;pregnancy and lactation

Intervention groups

This study will be a randomized, double -blind clinical trial with parallel groups; 116 people will be randomly divided into two groups. Patients in the intervention group will take Rhamnus frangula extract sachetes before colonoscopy and control group will receive Pidrolax sachetes before colonoscopy.

Main outcome variables

bowel preparation BOSTON score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220104053626N4**

Registration date: **2022-12-21, 1401/09/30**

Registration timing: **prospective**

Last update: **2022-12-21, 1401/09/30**

Update count: **0**

Registration date

2022-12-21, 1401/09/30

Registrant information

Name

Masood Dinevari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

dinvarim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effectiveness and patient tolerance of oral lavage of Rhamnus frangula extract and polyethylene glycol for colonoscopy preparation. A randomized controlled trial study

Public title

effectiveness and patient tolerance of oral lavage of Rhamnus frangula extract for colonoscopy preparation

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

age 18-75 willingness to participate

Exclusion criteria:

any history of drug reaction history of dysphagia and swallowing dysfunction history of ileus and bowel obstruction and gastroparesia active inflammatory bowel disease electrolyte imbalance renal and liver failure pregnancy and lactation

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

From the patients who volunteered to participate in the study, 116 persons will be selected by simple random sampling. Randomization method: block Randomization unit : Individual Randomization layers: In each block, people will be matched based on age and gender. Random Allocation software: Random Allocation software How to create a random sequence: Using Random Allocation software Hide: The random sequence created is kept in a safe place and is done by an independent person who is not involved in the experiment during the study. Random allocation of hidden individuals, patients and researchers will not be aware of it.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind study in which the researcher of this study and the patients participating in the study will be unaware of the type of supplement received. Supplements will be provided to patients by another person who has no role in completing the questionnaire

and performing colonoscopy. Patients will also be informed of the existence of two types of supplements (polyethylen glycol and Rhamnus frangula extract) when obtaining consent, but will be unaware of which study groups they will be included in. Rhamnus frangula extract sachetes are similar in appearance color, and size to polyethylen glycol sachetes.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Ethic committee, Vice chancellor for research, Faculty of medicine, Tabriz University of Medical Sciences, Golgasht st, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5163996889

Approval date

2021-12-13, 1400/09/22

Ethics committee reference number

IR.TBZMED.REC.1400.936

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

bowel preparation for colonoscopy

ICD-10 code

Z12.11

ICD-10 code description

Encounter for screening for malignant neoplasm of colon

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

bowel preparation score

Timepoint

after intervention

Method of measurement

BOSTON score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients will receive 4 sachetes each contain of 500mg Rhamnus frangula extract which will dissolve in a liter of water. they will receive a glass every 6 hours 24 hours before the colonoscopy ,In order to prepare Rhamnus frangula sachet, frangula fruit will be purchased from reputable centers and then dried in a drying machine and ground in a special herb grinder and packed as a powder in the sachetes.

Category

Treatment - Drugs

2

Description

2nd intervention group: . All patients will receive 4 sachetes of Pidrolax each dissolved in 1litre water and will take a glass every 20 minutes 24 hours before colonoscopy. Pidrolax sachets containing polyethylene glycol 4000 will belong to Sepidaj company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Masood Faghih Dinevari

Street address

Emam reza hospital, Golgast st,Tabriz.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

Vice chancellor for Research,Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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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

Tabriz University of Medical Sciences

Proportion provided by this source

50

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

Tabriz University of Medical Sciences

Full name of responsible person

Masood faghih Dinevari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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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

no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable