

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Assessment of peppermint extract effect on colonoscopy quality in patients referring to Urmia Imam Khomeini hospital

Protocol summary

Study aim

Determining peppermint extract effect on colonoscopy quality in patients referring to Urmia Imam Khomeini hospital

Design

This study will be performed as a double-blind clinical trial with parallel groups (phase 3) on 128 patients. Patients will be divided into two groups of intervention and placebo using a simple random method and a random number table.

Settings and conduct

In this study, 128 patients referred to the colonoscopy ward of Urmia Imam Khomeini hospital will be included in the study. Patients will be randomly divided into an intervention group (50 cc peppermint extract) and placebo group (50 cc drinking water) using a random number table. Peppermint and placebo extract will be applied to various parts of the large intestine during colonoscopy.

Participants/Inclusion and exclusion criteria

Patients aged between 18 and 65 who are suspected of having colon polyps, colon disease, or bleeding of unknown origin will undergo colonoscopy. Inclusion criteria: not consuming antispasmodics, suspicion of colon polyps, colon diseases, bleeding of unknown origin. Exclusion criteria: having irritable bowel syndrome, lack of mental health and full consciousness, use of anti-anxiety and analgesic drugs, having a history of allergies to any type of drugs

Intervention groups

In the intervention group, 50 cc of peppermint extract and in the control group, 50 cc of drinking water will be injected into the colon during colonoscopy through the working channel in various areas of the large intestine.

Main outcome variables

Total procedure time, pain, time to reach the cecum

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201204049599N5**

Registration date: **2021-06-14, 1400/03/24**

Registration timing: **prospective**

Last update: **2021-06-14, 1400/03/24**

Update count: **0**

Registration date

2021-06-14, 1400/03/24

Registrant information

Name

Mohammad Reza Pashae

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3198 8001

Email address

pashae.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-26, 1400/05/04

Expected recruitment end date

2021-10-05, 1400/07/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of peppermint extract effect on colonoscopy quality in patients referring to Urmia Imam Khomeini hospital

Public title

Assessment of peppermint extract effect on colonoscopy quality

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 18 to 65 years, not consuming antispasmodics, suspicion of intestinal polyps, large bowel diseases, unknown origin gastrointestinal bleeding

Exclusion criteria:

Irritable Bowel Syndrome, lack of having mental health and full consciousness, consumption of anti-anxiety and painkillers, having a history of allergy to any drug

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed in a simple randomization method by using a table of random numbers. Each patient will first be assigned a three-digit code. The first patient will have code 001 and the last patient will have code 128. A number will then be selected randomly. The first three digits will be examined. It will be continued from top to bottom in the table to complete the sample size. If the number is less than or equal to 128, that number will be selected. The duplicate number will be ignored and another number from the table will be checked. Numbers between 001 and 064 will be assigned to the intervention group and numbers between 065 and 128 will be assigned to the placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be double-blind. The patient and the endoscopist will be blind that which groups each patient belongs to. Peppermint extract and placebo will be the same in volume and color. Due to the smell of peppermint extract, in order the endoscopist not be noticed the placebo and the peppermint, before starting the endoscopy, some peppermint extract will be sprayed into the endoscopy room to smell only peppermint extract.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Resalat Ave., University of Medical Sciences, Urmia

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Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2020-02-19, 1398/11/30

Ethics committee reference number

IR.UMSU.REC.1399.027

Health conditions studied

1

Description of health condition studied

Colonoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Total time of the procedure

Timepoint

During Colonoscopy

Method of measurement

Minute

Secondary outcomes

1

Description

Pain

Timepoint

During Colonoscopy procedure

Method of measurement

Score based on visual analog scale (VAS)

2

Description

Time to reach Cecum

Timepoint

During colonoscopy

Method of measurement

Minute

Intervention groups**1****Description**

Intervention group: 50 cc of peppermint extract in various areas of the colon during colonoscopy will be injected into the large intestine through the working channel of the colonoscope.

Category

Treatment - Other

2**Description**

Control group: 50 cc of drinking water will be injected into the large intestine through the working channel of the Colonoscopy device in different areas of the large intestine during colonoscopy.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Mohammad Reza Pashaei

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Imam Khomeini Hospital; Ershad Blvd., Urmia, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

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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

Oroumia 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**

Oroumia University of Medical Sciences

Full name of responsible person

Mohammad Reza Pashaei

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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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

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