

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Premedication with Peppermint oil capsules (Colpermin®) in colonoscopy: A Double blind placebo-controlled randomized trial study

Protocol summary

Summary

The main problem in colonoscopy for endoscopists to advance the colonoscope and visualize the mucosa is colonic spasm. The aim of this study was to evaluate the efficacy of Colpermin as an orally administered antispasmodic premedication to reduce colon spasm and pain and increase satisfaction in a randomized double blinded placebo controlled trial. Patients on whom total colonoscopy was not possible (due to obstruction by tumor or being high risk for perforation as in severe colitis or history of colectomy), pregnant and lactating women, and peppermint allergy history were excluded from the study. Patients were randomly allocated by opening a sealed envelope with a computer-generated code in groups to received either colpermin or placebo. The placebos were prepared in capsules with similar appearance to Colpermin which were filled with lactulose. Capsules were administered 4 hours before colonoscopy. Time required for intubation to the cecum and the total procedure time recorded by the endoscopist. After the colonoscopy, patients were asked to rate their pain by using a numerical rating scale. colonoscopist satisfaction and colon spasm score were assessed by the endoscopist immediately after the procedure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107056957N1**
Registration date: **2011-07-16, 1390/04/25**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-16, 1390/04/25

Registrant information

Name

Samaneh Khanpour Ardestani

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2008-08-03, 1387/05/13

Expected recruitment end date

2009-08-04, 1388/05/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Premedication with Peppermint oil capsules (Colpermin®) in colonoscopy: A Double blind placebo-controlled randomized trial study

Public title

Colpermin in colonoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who have indication for colonoscopy by expert physician; age more than 18 and signing the informed consent. Exclusion criteria: Patients that total colonoscopy is not possible for them (due to

obstruction by tumor or being high risk for perforation as in severe colitis or history of colectomy); pregnant and lactating women, and peppermint allergy history

Age

From **18 years** old to **81 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences Hezae jarib
Street Isfahan

City

Isfahan

Postal code

Approval date

2007-05-27, 1386/03/06

Ethics committee reference number

286006

Health conditions studied

1

Description of health condition studied

patients with digestive diseases who need colonoscopy

ICD-10 code

k00-k93

ICD-10 code description

Crohn's disease [regional enteritis] , Ulcerative colitis ,
Other noninfective gastroenteritis and colitis, Vascular disorders of intestine , Diverticular disease of intestine ,
Other diseases of anus and rectum , Other diseases of digestive system

Primary outcomes

1

Description

pain

Timepoint

after colonoscopy

Method of measurement

numerical rating scale

2

Description

Time required for intubation to the cecum and the total procedure time

Timepoint

after colonoscopy

Method of measurement

minites

3

Description

colon spasm

Timepoint

after colonoscopy

Method of measurement

numerical rating scale for spasm

Secondary outcomes

1

Description

drug adverse effect

Timepoint

before and after colonoscopy

Method of measurement

questionnaire

2

Description

bowel preparation

Timepoint

after colonoscopy

Method of measurement

numerical rating scale for bowel preparation

3

Description

colonoscopist satisfaction

Timepoint

after colonoscopy

Method of measurement

numerical rating scale for colonoscopist satisfaction

4

Description

patient willingness to repeat colonoscopy with the

present method
Timepoint
after colonoscopy
Method of measurement
questionnaire

Intervention groups

1

Description
Taking 2 colpermin (187 mg) capsules 4 hour before colonoscopy
Category
Treatment - Drugs

2

Description
Taking 2 placebo capsules (filling with lactulose) 4 hour before colonoscopy
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Alzahra hospital
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor research Isfahan University of Medical Sciences
Full name of responsible person
Dr Peiman Adibi vice chancellor research of Isfahan University of Medical Sciences
Street address
Hezar jarib street Isfahan University of Medical Sciences
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor research Isfahan University of Medical Sciences
Proportion provided by this source
100

Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Isfahan University of Medi
Full name of responsible person
Dr Samaneh Khanpour Ardestani
Position
general practitioner
Other areas of specialty/work
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Isfahan University of Medical Sciences
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Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person

Dr Samaneh Khanpour

Position

General practitioner

Other areas of specialty/work

Street address

City

Ardestan

Postal code

Phone

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty