

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Investigating the analgesic effect of coccidiary essential oil and lubricant gel in patients referred for colonoscopy; Randomized double-blinded clinical trial

Protocol summary

Study aim

Investigating the analgesic effect of coccidiary essential oil and lubricant gel in patients referred for colonoscopy; Randomized double-blinded clinical trial

Design

Our assumption is that coccidiary herbal medicine, due to the presence of analgesic chemical compounds, can make it easier and more satisfactory for patients to undergo colonoscopy by reducing their pain.

Settings and conduct

Digestive and Liver Research Center, GI and Liver Research Center, Elite Center and Fractional Service

Participants/Inclusion and exclusion criteria

this study, the first coctail drug from southern provinces was collected and after the extraction of essential oil, the essence of the substance was first identified by the method of liquid caratography and its main chemical compounds. Then, based on this and previous studies, the lubricant gel with different percentages (low And much) made from coctite essential oil. Essential Oil Preparation: For the extraction of cocoa juice after collecting and drying in the shade, the Clewinger method and steam distillation at 75 ° C for 3 hours are performed.

Intervention groups

Experimental groups: A total of 200 people who referred for colonoscopy (sample size with Cochran formula) were put in 4 groups (each group was 50 without any indication), group 1 received a lidocaine-free lubricant gel , The second group receiving 2% lidocaine gel, group 3 and 4, respectively, receiving a lubricant gel, receive a low and high concentration of cacti essential oil in the form of blind, triple-blinded. In this way, before completing colonoscopy, the consent form is completed and not a remedy for all patients who use the drug for the purpose of pain relief.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190722044309N1**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **retrospective**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Ali Ghorbani Ranjbary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 81261

Email address

ali.ghorbaniranjbary@mail.um.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-12, 1397/07/20

Expected recruitment end date

2019-04-30, 1398/02/10

Actual recruitment start date

2018-10-12, 1397/07/20

Actual recruitment end date

2019-04-30, 1398/02/10

Trial completion date

2019-04-30, 1398/02/10

Scientific title

Investigating the analgesic effect of coccidiary essential oil and lubricant gel in patients referred for colonoscopy; Randomized double-blinded clinical trial

Public title

Investigating the analgesic effect of coccidiary essential oil and lubricant gel in patients referred for colonoscopy

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Experimental groups: A total of 200 individuals were assigned in 4 groups to determine the colonoscopy (Sample sample size with Cochran formula) (each group of 50 was unrelated). Group 2 received a non-lidocaine-type lubricant gel receptor group Lidocaine contains 2% throat, group 3 and 4, receptor of glycolate reductant containing low and high Ziziphora tenuior.

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **200**

Actual sample size reached: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation method in this study will be the permutation block randomization method, in which "A" represents the intervention group receiving one (no lidocaine), and "B" represents the second group receiving lidocaine 2%. Slow. And "c" represents the third group with a low concentration of cocoa and "D" represents the group receiving the high concentration of the drug. This method is based on 9 blocks in 24 permutations, taking into account all possible displacements (ABCD, ACBD, ABDC, BACD,) and assigning zero to 24 (according to random number table) to each of these .displacements. , Runs (ABCD code 0, ACBD code 1, CABD code 2, ... up to 24) Then, using a random number table, 9 random numbers (rows or columns) are selected and the permissions assigned to each number are written. (Arrange the permutations side by side, left and right, respectively) and how to assign 200 people to four groups of A B C D

Blinding (investigator's opinion)

Double blinded

Blinding description

Using placebo, the patient and the clinician performing the colonoscopy are kept blind to the study group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Baghiyyatollah al-Azam Military Hospital

Street address

The Baghiyyatollah al-Azam Military Hospital is a military hospital in Mulla Sadra Street in Vanak, Tehran, Iran. The hospital has ties with the Baqiyatallah University of Medical Sciences.

City

TEHRAN

Province

Tehran

Postal code

141556437

Approval date

2017-08-16, 1396/05/25

Ethics committee reference number

IR.BMSU.REC.1396.719

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

CRC: IBD::Anal anesthesia

ICD-10 code

C18.9

ICD-10 code description

Malignant neoplasm of colon, unspecified

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

Pain during a colonoscopy

Timepoint

1

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving a low concentration of cacti essential oil .

Category

Treatment - Drugs

2

Description

Intervention group: receiving a high concentration of cacti essential oil .

Category

Treatment - Drugs

3

Description

Control group: Lidocaine-free lubricant gel recipient

Category

Treatment - Drugs

4

Description

Control group: Gel recipient containing 2% lidocaine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiyyatollah Al-Azam Military Hospital

Full name of responsible person

Mohammad Roshani

Street address

Mollasadra street

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8805 0435

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bmsu@ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Seyed Moayed Alavian

Street address

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8248 3131

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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

Bagheiat-allah 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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Seyed Moayed Alavian

Position

Professor of Gastroenterology and Hepatology

Latest degree

Subspecialist

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact

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Position

free

Latest degree

Medical doctor

Other areas of specialty/work

Medical Biology

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Person responsible for updating data

Contact

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

no

When the data will become available and for how long

5m

To whom data/document is available

all

Under which criteria data/document could be used

Article

From where data/document is obtainable

Article

What processes are involved for a request to access data/document

Article

Comments