

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the Effect of Peppermint Extract with Placebo on Reducing Postoperative Pain During Elective Cholecystectomy

Protocol summary

Study aim

The aim of this study was to determine the effect of mint extract on reducing the severity of postoperative pain in cholecystectomy

Design

This is a double-blind clinical trial carried out in Emdad hospital of Sabzevar City. This study conducted on a total of 107 patients (47 placebo and 60 drug patients), who were candidate for cholecystectomy. Drug and placebo (40 drops three times every 20 minutes) were administered to patients suffering from postoperative pain after the recovery or stimulation of the gag reflex and onset of pain. The effect of mint extract on pain intensity was evaluated using the visual analog scale

Settings and conduct

This is a double-blind clinical trial conducted in Emdad Hospital in Sabzevar city on 107 patients undergoing open cholecystectomy.

Participants/Inclusion and exclusion criteria

The personal satisfaction to participate in the study Not having any mental or other illnesses

Intervention groups

Intervention group: 60 people are in the intervention group. Mint extract (40 drops three times every 20 minutes) was administered to patients suffering from postoperative pain after the recovery or stimulation of the gag reflex and onset of pain. The effect of mint extract on pain intensity was evaluated using the visual analog scale. Control group: 60 people are in the control group. Placebo (40 drops three times every 20 minutes) was administered to patients suffering from postoperative pain after the recovery or stimulation of the gag reflex and onset of pain. The pain intensity is evaluated using visual pain scale.

Main outcome variables

The severity and duration of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170404033202N8**

Registration date: **2018-01-12, 1396/10/22**

Registration timing: **prospective**

Last update: **2018-01-12, 1396/10/22**

Update count: **0**

Registration date

2018-01-12, 1396/10/22

Registrant information

Name

Atefeh Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 9180

Email address

a.asadi.mm.1384@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigation

Expected recruitment start date

2018-02-19, 1396/11/30

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Peppermint Extract with Placebo on Reducing Postoperative Pain During Elective Cholecystectomy

Public title

Effect of mint extract on pain relief after elective cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Have personal consent Weight between 40 and 120 kg Age between 75 and 25 years Elective surgery

Exclusion criteria:

Physical and mental illness Use opioid or alcohol History of surgery less than 3 years ago Receive fentanyl more than 2 micrograms per kilogram body weight before surgery or antiemetic as a precursor.

Age

From **25 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **107**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, researcher and analyst are not aware of the contents of the capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Central Office of the University of Medical Sciences - Asadabadi Street

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617684155

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

IR.Medsab.Rec.1395.146

Health conditions studied

1

Description of health condition studied

Pain after elective cholecystectomy

ICD-10 code

K90-93

ICD-10 code description

K91.5 Postcholecystectomy syndrome

Primary outcomes

1

Description

Severity of pain

Timepoint

1 hour after the onset of the medication

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 60 people are in the intervention group. Mint extract (40 drops three times every 20 minutes) was administered to patients suffering from postoperative pain after the recovery or stimulation of the gag reflex and onset of pain. The effect of mint extract on pain intensity was evaluated using the visual analog scale.

Category

Treatment - Drugs

2

Description

Control group: 60 people are in the control group. Placebo (40 drops three times every 20 minutes) was administered to patients suffering from postoperative pain after the recovery or stimulation of the gag reflex and onset of pain. The pain intensity is evaluated using visual pain scale.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Emdad Shahid Beheshti hospital in Sabzevar

Full name of responsible person

Mohammad Nematshahi

Street address

Emdad Shahid Beheshti hospital, Kooshk Street

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Sabzevar

Province

Razavi Khorasan

Postal code

9617684155

Phone

+98 51 4422 9180

Email

9157638703mn@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshteh GHorat

Street address

Pardiss University, Koosar Street, Touhid Blvd

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+98 51 4401 1035

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ghorat.f@gmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar 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

Person responsible for general inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Atefeh Asadi

Position

G.P.

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Department of Health, Talghani Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Nematshahi

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Central building of the University, Asadabadi Street

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Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Atefeh Asadi

Position

G.P.

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Phone

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Fax**Email**

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Web page address**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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

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