

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of 30 mg oral dextromethorphan and placebo on postoperative analgesia after laparoscopic cholecystectomy at the Hamedan Besat hospital

Protocol summary

Study aim

The effect of 30 mg oral dextromethorphan and placebo on postoperative analgesia after laparoscopic cholecystectomy

Design

114 patients undergoing laparoscopic cholecystectomy in a double-blind randomized clinical trial were randomly divided into either intervention(30 mg or 10 cc of dextromethorphan syrup 2 hours before induction of anesthesia used) or control groups(10 cc of a neutral syrup is taken orally.).

Settings and conduct

In this study, patients olde candidate for laparoscopic cholecystectomy surgery who will be referred to the Besat Hospital of Hamadan during the study period, will be randomly assigned to randomized allocation blocks by random sampling.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with ASA class 1 and 2; Patients candidate for laparoscopic cholecystectomy.
Exclusion Criteria: Patients with systemic underlying disease; Patients with history of alcohol and drug use, sedation and anticonvulsants; History sensitivity to drugs

Intervention groups

Intervention group: 30 mg or 10 cc of dextromethorphan syrup 2 hours before induction of anesthesia used.
Control: 10 cc of a neutral syrup is taken orally.

Main outcome variables

Pain score using VAS, Systolic and Diastolic Blood Pressure, Nausea & vomiting, Heart Rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170603034303N3**

Registration date: **2019-08-28, 1398/06/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-28, 1398/06/06**

Update count: **0**

Registration date

2019-08-28, 1398/06/06

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3821 6955

Email address

m.rezaeei@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 30 mg oral dextromethorphan and placebo on postoperative analgesia after laparoscopic cholecystectomy at the Hamedan Besat hospital

Public title

The effect of 30 mg oral dextromethorphan and placebo

on postoperative analgesia after laparoscopic cholecystectomy

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ASA class 1 and 2 Patients candidate for laparoscopic cholecystectomy

Exclusion criteria:

Patients with systemic underlying disease Patients with history of alcohol and drug use, sedation and anticonvulsants History sensitivity to drugs

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

We write two letters A and on two other sheets of letter B. We mix the papers together and put them in the drawer of the table. With each of the qualified patients, one of the papers is taken out randomly and, According to the text, the patient is given one of two groups: A (Intervention) and B Control). Then, for four subsequent patients, the paper is returned to the bag again, and this process is repeated until the end of the sample volume.

Blinding (investigator's opinion)

Double blinded

Blinding description

In both groups A and B, medications after spinal anesthesia Medication or placebo will be prescribed. In order to prevent the medication being detectable for patients and investigators, they are prepared with same size and shape and on the adhesives A and B by the anesthetist. Since drugs are prescribed by an anesthetist, the clinician will not be aware of the type of prescribed medication that will measure and record the outcome of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Mahdieh Street

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2019-08-10, 1398/05/19

Ethics committee reference number

IR.UMSHA.REC.1398.430

Health conditions studied

1

Description of health condition studied

cholecystitis

ICD-10 code

K81.1

ICD-10 code description

Chronic cholecystitis

Primary outcomes

1

Description

Pain

Timepoint

1, 6 and 12 hours after surgery

Method of measurement

VAS score

Secondary outcomes

1

Description

Nausea & vomiting

Timepoint

After surgery

Method of measurement

Observation

2

Description

Systolic and Diastolic Blood Pressure

Timepoint

1 hours after surgery

Method of measurement

Barometer

3

Description

Heart Rate

Timepoint

1 hours after surgery

Method of measurement

Using a pulse oximeter

Intervention groups

1

Description

Intervention group: 30 mg or 10 cc of dextromethorphan syrup 2 hours before induction of anesthesia used

Category

Treatment - Drugs

2

Description

Control group: 10 cc of a neutral syrup 2 hours before induction of anesthesia used orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Mahmoud Rezaeei, Anesthesiologist, Assistant Professor of Hamadan University Of Medical Sciences

Street address

Besat Hospital in Hamadan

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6517789971

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+98 81 3827 7012

Email

m.rezaeei@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeed Bashirian

Street address

Mahdie Street

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6517838678

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vc_research@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Mahmoud Rezaeei

Position

Assistant Professor of Hamadan University Of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Mahmoud Rezaeei

Position

Assistant Professor of Hamadan University Of Medical Sciences

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Assistant Professor of Hamadan University Of Medical Sciences

Latest degree

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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