Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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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

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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 updating data

Contact

Name of organization / entity

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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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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