Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison the effect of preoperative oral clonidine and placebo on shoulder pain in laparoscopic cholecystectomy with general anesthesia

Protocol summary

Study aim

The purpose of this study will be to assess the effect of preoperative oral clonidine and placebo on shoulder pain in elective laparoscopic cholecystectomy with general anesthesia

Design

Clinical trial with two arm parallel groups, randomised trial with double blinded assessment. Study phase will be 2-3.

Settings and conduct

In Urmia Imam Khomeini hospital operating room the patients with elective laparoscopic cholecystectomy with general anesthesia will be devided into two parallel groups (32patients per group).The drug will be administered by the nurse in the ward and at the time of admission, the anesthesiologist will be unaware which patient will be assigned to which group. Drug containers will be identical and only the nurse will know about the contents of each of them, and finally, after collecting information by the resident in training in anesthesiology, the anesthesiology specialist will be informed of the group each patient is assigned to. After surgery shoulder pain will be compared with each other.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Being at the age of 20 to 60 years old, American Society of Anesthesiologists class I and II, Elective laparoscopic cholecystectomy surgery Exclusion criteria: Hypertension, Heart disease, Gastritis, kidney disease, Lung disease, Mental disease, Addicted to all kinds of opioid drugs, People treated with, beta-blockers, People treated with methyl dopa, Individuals treated with monoamine oxidase inhibitors, use of analgesic drugs, Body mass index above 25 kg / m 2

Intervention groups

Intervention group: patients will receive clonidine 150 Microgram oral tablet, 90 minutes before surgery. Control group: will be received oral placebo 90 minutes before surgery.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N17**
Registration date: **2019-12-14, 1398/09/23**
Registration timing: **retrospective**

Last update: **2019-12-14, 1398/09/23**
Update count: **0**

Registration date

2019-12-14, 1398/09/23

Registrant information

Name
Shahryar Sane
Name of organization / entity
Urmia University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 44 3223 4897
Email address
sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-20, 1396/01/31

Expected recruitment end date

2018-04-20, 1397/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison the effect of preoperative oral clonidine and placebo on shoulder pain in laparoscopic cholecystectomy with general anesthesia

Public title
Effect of preoperative oral clonidine on shoulder pain in laparoscopic cholecystectomy with general anesthesia

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Being at the age of 25 to 55 years old American Society of Anesthesiologists class I and II Elective laparoscopic cholecystectomy surgery

Exclusion criteria:
Hypertension Heart disease Gastritis kidney disease Lung disease Mental disease Addicted to all kinds of drugs People treated with beta-blockers People treated with methyl dopa Individuals treated with monoamine oxidase inhibitors use of analgesic drugs Body mass index above 25 kg / m 2

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Care provider
- Investigator

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned into two groups of clonidine 150 Micrograms (group C) and placebo (group P) using Random Allocation Software 2.0, and the target codes will be written on a piece of paper and placed in sealed envelopes with sequential allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drug will be administered by the nurse in the ward and at the time of admission, the anesthesiologist will be unaware which patient will be assigned to which group. Drug containers will be identical and only the nurse will know about the contents of each of them, and finally, after collecting information by the resident in training in anesthesiology, the anesthesiology specialist will be informed of the group each patient is assigned to.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics commitee of Urmia University of Medical Sciences

Street address
Orjanse alley, Resalat blvd

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2016-05-06, 1395/02/17

Ethics committee reference number
Ir.umsu.rec.1395.86

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
R52.9

ICD-10 code description
Generalized pain NOS

Primary outcomes

1

Description
pain

Timepoint
In recovery, 6, 12 and 24 hours after surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Mean Arterial Blood Pressure

Timepoint
Before anesthesia, In recovery, during Laryngoscopy, 6, 12 and 24 hours after surgery

Method of measurement
None Invasive Blood Pressure

2

Description

Mean pulse Rate

Timepoint

Before anesthesia, In recovery, during Laryngoscopy, 6, 12 and 24 hours after surgery

Method of measurement

Electrocardiogram

Intervention groups

1

Description

Intervention group: patients will receive clonidine 150 Microgram oral tablet, 90 minutes before surgery.

Category

Treatment - Drugs

2

Description

Control group: will be received oral placebo 90 minutes before surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating room, Khomeini Hospital

Full name of responsible person

Shahryar Sane

Street address

Ershad blvd, Modarres blvd

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3346 9931

Fax

+98 44 3346 8967

Email

emam-h-urm@umsu.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Orjanse alley, Resalat blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Fax

+98 44 3223 4897

Email

research@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Orjanse alley, Resalat blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Fax

+98 44 3346 8967

Email

sanesh@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences
Full name of responsible person
Shahryar Sane
Position
Associate professor
Latest degree
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Other areas of specialty/work
Anesthesiology
Street address
Orjanse alley, Resalat blvd
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Fax
+98 44 3346 8967
Email
sanesh@umsu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Shahryar Sane
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Orjanse alley, Resalat blvd
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Fax
+98 44 3346 8967
Email
sanesh@umsu.ac.ir

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
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