Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparative study on the prophylactic effect of Dexmedetomidine and Paracetamol on intraoperative hemodynamic control and postoperative pain in patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim
Comparison of prophylactic effect of Dexmedetomidine and Paracetamol on hemodynamic control during surgery and post operative pain in patients with laparoscopic cholecystectomy

Design
Two arm parallel group randomized trial

Settings and conduct
132 patients are divided into two groups of 66 people. Patients admitted to the Amiralmomenin Hospital of Arak are under study. In each group, hemodynamic therapy is measured before surgery, 30, 60, and 90 minutes postoperatively. Postoperative pain is measured by Visual Analogue Scale in recovery, 4, 12, and 24 hours postoperatively.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1: Patients from 18 to 70 years old 2: Both genders 3: Patients who are indicated for urgent or elective Laparoscopic Cholecystectomy 4: Acquiring the informed consent of participating in a clinical study Exclusion criteria: 1: Conversion from Laparoscopic to open surgery 2: Partial Cholecystectomy 3: Gangrenous Gall Bladder 4: Abscess 5: Trauma to major Bile ducts

Intervention groups
The Dexmedmotidine group, in which patients receive Dexmedetomidine before and after the onset of action. The Paracetamol group in which patients receive Paracetamol before and 6 hours to 24 hours.

Main outcome variables
Operative hemodynamics in which the MAP and heart rate are measured. Postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180115038381N1**
Registration date: **2019-02-18, 1397/11/29**
Registration timing: **retrospective**

Last update: **2019-02-18, 1397/11/29**
Update count: **0**

Registration date
2019-02-18, 1397/11/29

Registrant information

Name
Taha Hojjati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3223 1102

Email address
taha.hojjati@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-05-05, 1396/02/15

Expected recruitment end date
2018-02-20, 1396/12/01

Actual recruitment start date
2017-04-04, 1396/01/15

Actual recruitment end date
2017-11-22, 1396/09/01

Trial completion date
2017-12-22, 1396/10/01

Scientific title
A comparative study on the prophylactic effect of Dexmedetomidine and Paracetamol on intraoperative hemodynamic control and postoperative pain in patients

undergoing laparoscopic cholecystectomy

Public title
A comparative study on the prophylactic effect of Dexmedetomidine and Paracetamol on intraoperative hemodynamic control and postoperative pain in patients undergoing laparoscopic cholecystectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are indicated for emergency or elective Laparoscopic Cholecystectomy. Obtaining informed consent Both genders Patients between 18 to 70 years old
Exclusion criteria:
Conversion of Laparoscopic surgery to open surgery Partial Cholecystectomy Gangrenous Gall bladder Abscess Major trauma to Bile ducts
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **132**
Actual sample size reached: **132**
Randomization (investigator's opinion)
Randomized
Randomization description
Blocked Randomization Individual random unit Randomization tool under web (www.randomizer.org) Randomization sequence was made under web (www.radomizer.org) Hiding: Sealed envelope
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Arak University of Medical Sciences
Street address
Deputy Director of Research and Technology, University of Medical Sciences campus site, Basij Square, Arak
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2017-05-01, 1396/02/11
Ethics committee reference number
IR.ARAKMU.REC.1396.1

Health conditions studied

1

Description of health condition studied
Postoperative pain after Laparoscopic Cholecystectom
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Peri-operative Hemodynamic
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mean Arterial Blood Pressure
Timepoint
Immediately after Anesthesia induction, 30 minutes after surgery, 1 hour after surgery, 90 minutes after surgery
Method of measurement
Blood pressure gauge

2

Description
Pulse Rate
Timepoint
Immediately after Anesthesia induction, 30 minutes after surgery, 1 hour after surgery, 90 minutes after surgery
Method of measurement
Measured by the questioner

3

Description
Postoperative Pain
Timepoint
In Recovery Unit, 4 hour after surgery, 12 hour after surgery, 24 hour after surgery
Method of measurement
With Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group included 66 patients undergoing laparoscopic cholecystectomy and receiving doxedemotomidine. Patients in this group receive 1 µg / Kg stat and then 0.5 µg / Kg per hour. In this study, the American Percedex product, each vial containing 200 µg doxedetomidine, is used.
Category
Treatment - Drugs

2

Description
Second intervention group: includes 66 patients undergoing laparoscopic cholecystectomy and receiving paracetamol. These patients first receive 1 g of intravenous paracetamol before surgery and receive 500 mg paracetamol every 6 hours after surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin Hospital
Full name of responsible person
Taha Hojjati Ashrafi
Street address
Basig squre
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Postal code
3848176941
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it-amiralmomenin@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Mohammad Arjomandzadegan
Street address
Basij Square,
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Postal code
3848176341
Phone
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Email
mmatinam81@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Taha Hojjati Ashrafi
Position
Surgery Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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4, Zeytoon Appartment, Behdari Street
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Taha Hojjati Ashrafi
Position

Surgery Resident

Latest degree

Medical doctor

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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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