

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 Amirmomenin 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 Dexmedetomidine 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

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

General information

Reason for update

Acronym

IRCT registration information

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.randomizer.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 committee 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 Cholecystectomy
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 doxedetomidine. 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 square

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Markazi

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3848176941

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Fax

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Email

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,

City

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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

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Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Position
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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