

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison Intraperitoneal Ropivacaine alone and with Dexmedetomidin and Fentanyl on pain management in abdominal laparoscopic

Protocol summary

Study aim

Comparison of Intraperitoneal Ropivacaine alone and Intraperitoneal Ropivacaine with Dexmedetomidin and Fentanyl on pain management in abdominal laparoscopic

Design

This study is clinical trial and double blind. 138 patients candidate elective abdominal laparoscopy in Valiasr hospital will enter this study. We will divide patients in 3 groups by simple randomization. Groups are parallel.

Settings and conduct

138 patients candidate elective abdominal laparoscopy in Valiasr hospital. This study is double blind. Outcome assessor and analyzer do not aware from grouping. Codes of group are available to analyzer and outcome assessor. We record blood pressure, heart rate, oxygen saturation, pain and amount of opioids consumed during surgery in each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients candidate laparoscopic abdominal surgery, 18 to 65 years old, lack of susceptibility to used drugs, absence of cardiovascular disease and endocrine and renal disease, no smoking and no addiction, no pregnancy, body mass index more than 35. Exclusion criteria: not wanting to continue the study, refusal of the patient to inject intraperitoneally, patient that requires the insertion of a drain inside the abdomen for any reason.

Intervention groups

First group: 2 milligram per kilogram Ropivacaine 0.5 % (Molteni Co. Italia) use that total volume of it is adjusted to 50 milliliter with normal saline (Daropaksh Co.). Second group: 2 milligram per kilogram Ropivacaine 0.5 % (Molteni Co. Italia) plus 1 micro gram per kilogram Dexmedetomidine (Exir Co. Iran). Third group: 2 milligram per kilogram Ropivacaine 0.5 % (Molteni Co. Italia) plus 1 micro gram per kilogram Fentanyl (Aboreyhan Co. Iran).

Main outcome variables

Blood pressure; heart rate; oxygen saturation; pain; amount of opioids consumed during surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N117**

Registration date: **2019-07-13, 1398/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-13, 1398/04/22**

Update count: **0**

Registration date

2019-07-13, 1398/04/22

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2020-01-05, 1398/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Intraperitoneal Ropivacaine alone and with Dexmedetomidin and Fentanyl on pain management in abdominal laparoscopic

Public title

Comparison Intraperitoneal Ropivacaine alone and with Dexmedetomidin and Fentanyl on pain management in abdominal laparoscopic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate laparoscopic abdominal surgery 18 to 65 years old No susceptibility to used drugs Absence of cardiovascular disease and endocrine and renal disease No smoking and no addiction No pregnancy Body mass index more than 35

Exclusion criteria:

No willingness to continue the study Refusal of the patient to inject intraperitoneally Patient that requires the insertion of a drain inside the abdomen for any reason

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **138**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in three groups A and B and C. In this method, we wrote on some cards intervention group1 and the same number of cards for intervention group 2 and the same number of cards for the control group, then the cards were mixed in a container. One card was taken out and its allocation was registered and the card was returned to the container. Then the cards were mixed again and another card was taken. This process continued to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind).Outcome assessor and analyzer don't aware from grouping.The person evaluating the outcome is unaware of the grouping. Definition of groups A and B and C are available to analyzer and outcome assessor.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij squire, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

38149578558

Approval date

2018-12-30, 1397/10/09

Ethics committee reference number

IR.ARAKMU.REC.1397.267

Health conditions studied

1

Description of health condition studied

abdominal elective laparoscopic

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean arterial blood pressure

Timepoint

Every 30 minutes during surgery and recovery and 2 hours after surgery

Method of measurement

Barometer

2

Description

Heart rate

Timepoint

Every 30 minutes during surgery and recovery and 2 hours after surgery

Method of measurement

Count

3

Description

Percent of oxygen saturation

Timepoint

Every 30 minutes during surgery and recovery and 2 hours after surgery

Method of measurement

Pulse oximetry

4**Description**

Pain

Timepoint

At recovery and 2, 4, 6, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale Questionnaire

5**Description**

Amount of opioids consumed during surgery

Timepoint

End of surgery

Method of measurement

Milligram

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: 2 milligram per kilogram Ropivacaine 0.5 % (Molteni Co.Italia) use that total volume of it is adjusted to 50 milliliter with normal saline (Daropaksh.Co).

Category

Treatment - Drugs

2**Description**

Intervention group: 2 milligram per kilogram Ropivacaine 0.5 % (Molteni Co.Italia) plus 1 micro gram per kilogram Dexmedetomidine (Exir Co.Iran).

Category

Treatment - Drugs

3**Description**

Intervention group: 2 milligram per kilogram Ropivacaine 0.5 % (Molteni Co.Italia) plus 1 micro gram in kilogram Fentanyl (Aboreyhan Co.Iran).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Hesamodin Modir

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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
 Dr Bijan Yazdi
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 Associate professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Modir

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments