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 inter 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 (Daropakhsh.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

Country

Iran (Islamic Republic of)

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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 squre, 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 (Daropakhsh.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
Street address
Valiasr hospital, Valiasr squre
City
Arak
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3848176941
Phone
+98 86 3222 2003
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modir.he@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Arjmandzadegan
Street address
Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak
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arjmandzadegan@arakmu.ac.ir
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

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person
Dr Hesamedin Modir

Position
Associate professor

Latest degree
Specialist

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
Mahsa Piri

Position
Medicine student

Latest degree
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Other areas of specialty/work
General Practitioner

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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