

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the preemptive effect of Dexmedetomidine and ketorolac on post operative pain of appendectomy

Protocol summary

Study aim

Comparison of the Effectiveness of Pretreatment of Dexmedetomidine and Ketorolac on Postoperative Pain in Appendectomy

Design

The sampling method is purposeful and the patients eligible for the study according to entry and exit conditions are studied and then divided into three groups according to the randomized block table obtained by random allocation software.

Settings and conduct

This study is a randomized, double blind clinical trial. After approval by the College of Medicine and Ethics Committee of the University of Medical Sciences all patients aged 18 to 65 years with ASA 1 and 2 who are admitted to apprenticeship at Shahid Mohammadi Bandar Abbas Hospital in 2018 and undergo appendectomy. To be Patients first enter the operating room after being informed by the written consent form attached to it, randomly enter the block into one of the three groups A, B, or C

Participants/Inclusion and exclusion criteria

patients with ASA classification 1&2 18-65 Years old

Intervention groups

Prescribing dexmedetomidine, ketorolac and normal saline for three groups before and during surgery

Main outcome variables

Age Sex Weight Intensity of pain blood pressure heart beat Intervention (drug combination) The amount of pca content nausea and vomiting Shivering Temperature

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140615018091N9**

Registration date: **2019-01-10, 1397/10/20**

Registration timing: **retrospective**

Last update: **2019-01-10, 1397/10/20**

Update count: **0**

Registration date

2019-01-10, 1397/10/20

Registrant information

Name

Fekrat Fereydoon

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-03, 1397/05/12

Expected recruitment end date

2018-09-03, 1397/06/12

Actual recruitment start date

2018-08-04, 1397/05/13

Actual recruitment end date

2018-09-12, 1397/06/21

Trial completion date

2018-10-02, 1397/07/10

Scientific title

Comparison of the preemptive effect of Dexmedetomidine and ketorolac on post operative pain of appendectomy

Public title

the preemptive effect of Dexmedetomidine and ketorolac on post operative pain of appendectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Appendicitis patients with ASA classification 1 & 2 18-65 years old

Exclusion criteria:

History of allergy to any of the drugs used in the study
Patient with ASA classification above two Addicted patients Neuropathy or misuse of pain medication
Treatment with analgesics or anti-inflammatory drugs
Pregnancy and lactation Patients with complicated appendectomy

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The pump syringes were prepared by an expert in the anesthetic room and the assistant did not know its content.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bandar Abbas University of Medical Sciences

Street address

Anesthesiology Research Center, Shahid Mohammadi Hospital, Islamic Republic Blvd.

City

Bandarabbas

Province

Hormozgan

Postal code

7916613885

Approval date

2018-05-29, 1397/03/08

Ethics committee reference number

IR.HUMS.REC.1397.047

Health conditions studied

1

Description of health condition studied

post operative pain of appendectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

vas score

Timepoint

at 1, 3, 6, 12 and 24 hours after operation

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

PCA use

Timepoint

at 24 hours after operation

Method of measurement

ml

2

Description

Age

Timepoint

Before entering the study

Method of measurement

ID card

3

Description

Weight

Timepoint

After entering the study and obtaining consent

Method of measurement

kg

4

Description

blood pressure

Timepoint

before intubation, immediately after intubation, at 5, 10, 15, 20, 30, 40 and every 10 minutes till the end of operation

Method of measurement

monitoring - mmHg

5**Description**

Heart rate

Timepoint

before intubation, immediately after intubation, at 5, 10, 15, 20, 30, 40 and every 10 minutes till the end of operation

Method of measurement

monitoring - Number per minute

6**Description**

Body temperature

Timepoint

before intubation, immediately after intubation, at 5, 10, 15, 20, 30, 40 and every 10 minutes till the end of operation

Method of measurement

Thermometer - C

7**Description**

SpO2

Timepoint

before intubation, immediately after intubation, at 5, 10, 15, 20, 30, 40 and every 10 minutes till the end of operation

Method of measurement

Pulse Oxymetry

8**Description**

nausea - vomiting

Timepoint

In recovery and 24 hours after surgery

Method of measurement

questionnaire

9**Description**

shivering

Timepoint

In recovery and 24 hours after surgery

Method of measurement

questionnaire

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

The first intervention group received intravenous dexmedetomidine(Precedex (dexmedetomidine hydrochloride) Hospira, Inc. Lake Forest, IL 60045 USA) 1 µg / kg as bolus dose within 10 minutes immediately

before induction and then 5 /. Micrograms per kilogram received continuous infusion during surgery.

Category

Treatment - Drugs

2**Description**

Intervention group2: Group B received intravenous 30 mg ketorolac before induction

Category

Treatment - Drugs

3**Description**

Control group: . Group C was the control group that received normal saline, before induction.

Category

Placebo

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

Shahid Mohamadi hospital, Bandar Abbas;IRAN

Full name of responsible person

Fereydoon Fekrat

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Islamic Republic Of Blvd , Shahid Mohammadi Hospital , Bandar Abbas Town , Research Center , Iran

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

Bandare-abbas University of Medical Sciences

Full name of responsible person

AbdulAzim Nejati Zadeh

Street address

Islamic Republic Blvd , Center for Research Vice , Shahid Mohammadi Hospital , Bandar Abbas Town ,Islamic Republic of Iran

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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

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Fereydoon Fekrat

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Hashem Jarineshin

Position

Associate Professor

Latest degree

Subspecialist

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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Full name of responsible person

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Position

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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

No - There is not 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

spss

When the data will become available and for how long

1/1/2018

To whom data/document is available

Researchers and referees

Under which criteria data/document could be used

Obtaining a written permit and mentioning the name in the sources

From where data/document is obtainable

fereydoon fekrat fereydoonfekrat@yahoo.com

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

Email your request

Comments