Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparative study of the analgesic effect of morphine and paracetamol in combination with ketorolac and paracetamol in open prostatectomy surgery

Protocol summary

Study aim

Comparative study of the analgesic effect of morphine and paracetamol in combination with ketorolac and paracetamol in open prostatectomy surgery

Design

Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 60 patients candidate for open prostatectomy.

Settings and conduct

In this study, 60 prospective candidates for open prostatectomy were referred to the Ali ibn Abi Talib hospital in Zahedan whom have inclusion criteria are enrolled. Participants are randomly divided into intervention and control groups. Individuals in the intervention group (the Ketorolac group) will receive one mg/kg body weight of ketorolac plus 35 mg per kg of paracetamol, and the control group (morphine group) will also receive 0.1 mg / kg Of body weight will receive morphine with 35 mg per kg of paracetamol. 4, 8, 12, 24, 36 and 48 hours after surgery, pain intensity will be measured in two groups using visual analogue pain scale and compared in two groups.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: All candidate patients for open prostatectomy referring to Ali ibn Abi Talib (AS) hospital in Zahedan. Major exclusion criteria: Drug use, narcotic drugs or psychiatric drugs; Renal failure; Hepatic failure; Gastrointestinal disease; Opioid, ketrolac and paracetamol allergy; Spinal anesthesia contraindication; General anesthetic contraindication; Failure of spinal anesthesia and switch to general anesthesia; Respiratory depression while receiving a pump of pain.

Intervention groups

The intervention group (the Ketorolac group) received one mg / kg body weight of ketorolac plus 35 mg per kg of body weight paracetamol The control group (morphine group) received 0.1 mg / kg body weight of morphine with 35 mg per kg body weight paracetamol.

Main outcome variables

The severity of postoperative pain; the amount of need for excess analgesia; sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180206038647N1**
Registration date: **2018-03-18, 1396/12/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-18, 1396/12/27**
Update count: **0**

Registration date

2018-03-18, 1396/12/27

Registrant information

Name

Siavash Jamalzehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5725

Email address

dr.jamalzehi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-28, 1396/08/06

Expected recruitment end date

2018-10-28, 1397/08/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the analgesic effect of morphine and paracetamol in combination with ketorolac and paracetamol in open prostatectomy surgery

Public title

Effect of morphine in combination with paracetamol in postoperative analgesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All candidate patients for open prostatectomy referring to Ali ibn Abi Talib (AS) hospital in Zahedan

Exclusion criteria:

Drug use, narcotic drugs or psychiatric drugs Renal failure Hepatic failure Gastrointestinal disease Opioid, ketrolac and paracetamol allergy Spinal anesthesia contraindication General anesthetic contraindication Failure of spinal anesthesia and switch to general anesthesia Respiratory depression while receiving a pump of pain

Age

No age limit

Gender

Male

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block

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 Zahedan Medical University of Science

Street address

Ethics Committee of Zahedan Medical University of Science, Zahedan Medical University of Science, Dr.Hesabi Square, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2017-09-26, 1396/07/04

Ethics committee reference number

IR.ZAUMS.REC.1396. 42

Health conditions studied

1

Description of health condition studied

Open prostatectomy

ICD-10 code

N52.34

ICD-10 code description

Erectile dysfunction following simple prostatectomy

Primary outcomes

1

Description

Severity of postoperative pain

Timepoint

4, 8, 12, 24, 36 and 48 hours after surgery

Method of measurement

Visual Analogue Scale

2

Description

Sedation

Timepoint

4, 8, 12, 24, 36 and 48 hours after surgery

Method of measurement

Ramssay score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: received one mg / kg body weight of ketorolac plus 35 mg per kg of body weight paracetamol

Category

Treatment - Drugs

2

Description
Control group: received 0.1 mg / kg body weight of morphine with 35 mg per kg body weight paracetamol
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali ebn abi talib Zahedan Hospital
Full name of responsible person
Dr Asadollah Shakeri
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Ali-ebn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi Sq., Zahedan
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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
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Siavash Jamalzehi
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Anesthesiology Residence
Latest degree
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Person responsible for updating data

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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