

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, ketorolac 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 Jamalzahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5725

Email address

dr.jamalzahi@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, ketorolac 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

Street address

Ali-ebn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi Sq., Zahedan

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Email

Dr.shakeri@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Mohsen Taheri

Street address

Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan

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dr.taheri@zaums.ac.ir

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 Jamalzahi

Position

Anesthesiology Residence

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Asadollah Shakeri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Operation room, Ali-ebn Abi Taleb Hospital, Hesabi Sq., Daneshgah Ave., Zahedan, Sistan and Balouchestan

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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Position

Anesthesia Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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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