Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the postoperative analgesia effect of the combination of sufentanil and paracetamol with the combination of ketorolac and paracetamol in open prostatectomy surgery

Protocol summary

Study aim
Comparative study of the analgesic effect of sufentanil 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 (sufentanil group) will also receive 0.1 mg / kg Of body weight will receive sufentanil 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 (sufentanil group) received 0.1 mg / kg body weight of sufentanil 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: **IRCT20171111037369N2**
Registration date: **2018-02-28, 1396/12/09**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-28, 1396/12/09**
Update count: **0**

Registration date
2018-02-28, 1396/12/09

Registrant information

Name
Shadab Jafarizade

Name of organization / entity
Zahedan university of medical science

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-06-25, 1396/04/04

Expected recruitment end date
2018-06-25, 1397/04/04

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the postoperative analgesia effect of the combination of sufentanil and paracetamol with the combination of ketorolac and paracetamol in open prostatectomy surgery

Public title
Evaluation of the analgesic effect of sufentanil and paracetamol in comparison with the combination of ketorolac and paracetamol in open prostatectomy surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All patients candidate for open prostatectomy
Exclusion criteria:
usage of opioid, analgesic or psychiatric drugs renal failure hepatic diseases gastrointestinal diseases patient who have allergic history to opium, ketorolac, paracetamol contraindications for spinal anesthesia contraindications for general anesthesia spinal anesthesia failure and convertion to general anesthesia respiratory depression during IV-PCA infusion
Age
No age limit
Gender
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
block randomization with quadrilateral blocks
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
2017-06-25, 1396/04/04
Ethics committee reference number
IR.ZAUMS.REC.1396. 75

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
First Intervention group: received one mg / kg body

weight of ketorolac plus 35 mg per kg of body weight paracetamol

Category

Treatment - Drugs

2

Description

Intervention group: received 0.1 mg / kg body weight of sufentanil 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Mohsen Taheri

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

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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

Shadab Jafarizadeh

Position

Anesthesiology Residence

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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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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
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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