

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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, 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 (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)

Phone

+98 54 3322 3002

Email address

shadab.jfz@zaums.ac.ir

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 conversion 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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5721

Email

mrs.ameri2010@gmail.com

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5721

Email

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

Shadab Jafarizadeh

Position

Anesthesiology Residence

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5721

Email

mrs.ameri2010@gmail.com

**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

City

Zahedan

Province
Sistan-va-Balouchestan
Postal code
9816743111
Phone
+98 54 3329 5730
Fax
Email
Dr.Shakeri@zaums.ac.ir

Sistan-va-Balouchestan
Postal code
9816743111
Phone
+98 54 3329 5731
Email
shadab.jfz@zaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Shadab Jafarizadeh
Position
Anesthesia Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Operation room, Ali-ebn Abi Taleb Hospital, Hesabi
Sq., Daneshgah Ave., Zahedan, Sistan and
Balouchestan
City
Zahedan
Province

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