

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the postoperative analgesia effect of the combination of Ibuprofen and paracetamol with the combination of Morphine and paracetamol in open prostatectomy surgery

Protocol summary

Study aim

Comparative study of the analgesic effect of Ibuprofen and paracetamol in combination with Morphine and paracetamol in open prostatectomy surgery

Design

Phase 2-3 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 divided into two intervention groups. Individuals in the intervention group one (the Ibuprofen group) will receive 30 mg/kg body weight of Ibuprofen plus 35 mg per kg of paracetamol, and the intervention group two (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 disorders; Opioid, ketolac and paracetamol allergy; Spinal anesthesia contraindication; General anesthesia contraindication; Failure of spinal anesthesia and switch to general anesthesia; Respiratory depression while receiving a pump of pain.

Intervention groups

The first group (the Ibuprofen group) received 30 mg / kg body weight of Ibuprofen plus 35 mg / kg of body weight paracetamol The second group (Morphine group) received 0.1 mcg / 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: **IRCT20201011048988N1**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

Registration date

2020-12-12, 1399/09/22

Registrant information

Name

Zahra Hajinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3328 8535

Email address

med@iauzah.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-16, 1399/08/26

Expected recruitment end date

2021-02-18, 1399/11/30

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 Ibuprofen and paracetamol with the combination of Morphine and paracetamol in open prostatectomy surgery
Public title
Comparison of the postoperative analgesia effect of the combination of Ibuprofen and paracetamol with the combination of Morphine and paracetamol in open prostatectomy surgery

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All candidate patients for open prostatectomy.
Exclusion criteria:
Drug use, narcotic drugs or psychiatric drugs Renal failure Hepatic failure Gastrointestinal disease Opioid, Ibuprofen 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
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
N/A

Randomization description

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

2020-11-15, 1399/08/25

Ethics committee reference number

IR.ZAUMS.REC.1399.358

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 30 mg / kg body weight of Ibuprofen plus 35 mg per kg of body weight paracetamol

Category

Treatment - Drugs

2

Description

Intervention 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 Hospital

Full name of responsible person

Dr. Asadollah Shakeri

Street address

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

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

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

Islamic Azad university of Zahedan

Full name of responsible person

Zahra Hajinejad

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Islamic Azad university, Daneshgah Blvd, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743578

Phone

+98 54 3341 9432

Email

Zahra.Hnd@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Asadollah Shakeri

Position

Assistant 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

Email

Dr.Shakeri@zaums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad university of Zahedan

Full name of responsible person

Zahra Hajinejad

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Islamic Azad university, Daneshgah Blvd, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743578

Phone

+98 54 3341 9432

Email

Zahra.Hnd@gmail.com

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

Yes - There is 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

Main outcome information

When the data will become available and for how long

12 months after publishing results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

To verify the results and prevent repetition in similar research

From where data/document is obtainable

Library and website of Zahedan University of Medical Sciences

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

Refer to the library and website of Zahedan University of Medical Sciences and have access to a maximum of one week

Comments