Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effectiveness of intravenous paracetamol before surgery on the dose of opioid during and after radical prostatectomy.

Protocol summary

Study aim
Comparison of the effectiveness of intravenous paracetamol before surgery on the dose of opioid during and after radical prostatectomy.

Design
This study is a double-blind randomized clinical trial in which the number of patients is determined according to the sample size formula and using a simple randomization method, which uses a random number table for each patient. The code is given and patients are randomly assigned to two treatment groups, with random code selection.The number of samples in this study is 36 patients.

Settings and conduct
First, the intensity of preoperative pain in all patients will be determined before surgery, based on the visual analogue scale system. All patients undergo general anesthesia.Then, one hour before the surgery, in the first group, an intravenous paracetamol will be injected at a rate of one gram and then they will receive one gram an hour after the anesthesia injection and the second group will receive the same amount of placebos. During surgery, the dose of Injectable Opioid that includes Opioid administration every hour during surgery (Fentanyl based on the patient's weight) as well as the required postoperative Opioid based on the VAS required for the patient will be determined and recorded in two groups. Also, the severity of pain after surgery will be determined and recorded at recovery times, 2, 8, and 24 hours after recovery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 40 years Exclusion criteria: History of chronic drug use, Liver disorder, Kidney disorder

Intervention groups
Group 1: One hour before surgery, they will receive one gram of intravenous paracetamol and one gram after anesthesia. Group 2: One hour before surgery, placebo will be given one gram and one gram after anesthesia.

Main outcome variables
Severity of pain, dose of opioids, length of hospital stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160602028225N2**
Registration date: **2020-05-29, 1399/03/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-29, 1399/03/09**
Update count: **0**

Registration date
2020-05-29, 1399/03/09

Registrant information

Name
reza mohaghegh

Name of organization / entity
iums

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-20, 1399/02/31

Expected recruitment end date
2020-10-20, 1399/07/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of intravenous paracetamol before surgery on the dose of opioid during and after radical prostatectomy.

Public title

Effect of intravenous paracetamol on pain during and after prostate surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 40 years

Exclusion criteria:

History of chronic drug use Liver disorder Kidney disorder

Age

From **40 years** old

Gender

Male

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use the block randomization method to create equal groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block, we divide 4 people into groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and the person analyzing the study information are unaware of the study groups and are identified as groups A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

City

Tehran

Province

Tehran

Postal code

1433933111

Approval date

2020-05-16, 1399/02/27

Ethics committee reference number

IR.IUMS.FMD.REC.1399.137

Health conditions studied

1

Description of health condition studied

Prostate Cancer

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

Primary outcomes

1

Description

Severity of pain

Timepoint

Before and after surgery

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

Doses of opioids

Timepoint

During and after surgery

Method of measurement

File registration

2

Description

Hospital length

Timepoint

After surgery

Method of measurement
Hospital follow-up

Intervention groups

1

Description
Intervention group: In the first group, intravenous paracetamol will be injected at a rate of one gram, and then one gram will be given one hour after the anesthesia injection. During surgery, the amount of injectable fentanyl (500 micrograms per 10 cc ampoule made by Caspian Pharmaceutical Company) is based on the patient's weight every hour during the operation, as well as the injected petidine (50 mg per cc made by Caspian Pharmaceutical Company) based on VAS will be determined and recorded for the patient. Also, the severity of pain after surgery will be determined and recorded at recovery times, 2, 8, and 24 hours after recovery. Also, the prescribed dose of opioids will be determined during the 24 hours after the operation at the time of hospitalization, and finally the total length of hospital stay will be determined.
Category
Treatment - Drugs

2

Description
Control group: In the second group, the placebo will be injected at a rate of one gram, and then one gram will be given an hour after the anesthesia injection.During surgery, the amount of injectable fentanyl (500 micrograms per 10 cc ampoule made by Caspian Pharmaceutical Company) is based on the patient's weight every hour during the operation, as well as the injected petidine (50 mg per cc made by Caspian Pharmaceutical Company) based on VAS will be determined and recorded for the patient. Also, the severity of pain after surgery will be determined and recorded at recovery times, 2, 8, and 24 hours after recovery. Also, the prescribed dose of opioids will be determined within 24 hours after the operation at the time of hospitalization, and finally the total length of hospital stay will be determined.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hasheminejad Hospital
Full name of responsible person
Reza Mohaghegh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Reza Mohaghegh
Position
Associate professor
Latest degree
Specialist

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