Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

The Comparative Effect of Paracetamol vs Moderate Hydration on Post operative Pain in Open Prostatectomy, A Double Blind Clinical Trail

Protocol summary

Summary

The aim of this study is to compare effect of paraacetamol an moderate hydration.In double blind randomized clinical trail, 78 patients candidate for elective open prostatectomy who divide to equals group (n=39). Inclusion criteria are age between 45 till 75 that accept to come to study and Exclusion criteria are history of sensitivity to study medication, patients that received analgesic 8 hours before surgery; patients with psychological problem , any situation that made regional anesthesia contraindicated All the patients in control group receive moderate hydration plus bupiuvacaine .05% up to 3 milliliter. Paraacetamol(intravenous acetaminophen) has some analgesic effects and approved in 2006. In case group all the patients receive paraacetamol after surgery surgery and intratechal bupiuvacaine .05% up to 3 milliliter before surgery. Pain score, need to analgesic drugs, patient satisfaction and time of discharge, will be recorded and analyzed in study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306231936N12**
Registration date: **2015-08-08, 1394/05/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-08, 1394/05/17

Registrant information

Name

Abdolreza Najafi Anaraki

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Bushehr University of medical science

Expected recruitment start date

2015-07-15, 1394/04/24

Expected recruitment end date

2015-09-15, 1394/06/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparative Effect of Paracetamol vs Moderate Hydration on Post operative Pain in Open Prostatectomy, A Double Blind Clinical Trail

Public title

The Comparative Effect of Paracetamol vs Moderate Hydration on Post operative Pain in Open Prostatectomy, A Double Blind Clinical Trail

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: elective prostatectomy; age between 45 till 75 Exclusion criteria: history of sensitivity to medication study; patients that received analgesic 8 hours before surgery; patients with psychological problem; addiction and any situation that made regional anesthesia contraindicated

Age
From **45 years** old to **75 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Bushehr University of Medical Sciences
Street address
Bushehr University of Medical Sciences
City
Bushehr
Postal code
27/3/92
Approval date
2013-06-17, 1392/03/27
Ethics committee reference number
B-15-92-5

Health conditions studied

1

Description of health condition studied
Effect of Apotel and Paraacetamol on Post operative Pain in Open Prostatectomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Post Operative Pain
Timepoint
24 hours
Method of measurement
Visual

Secondary outcomes

1

Description
Patient Satisfication
Timepoint
24 hours
Method of measurement
Question

Intervention groups

1

Description
In control group all patients receive 20 Milliliters per kilogram normal slain
Category
Treatment - Drugs

2

Description
In intervention group all patient receives 10 milliliters per kilogram intravenous acetaminophen
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bushehr University of Medical Science
Full name of responsible person
Dr. Abdolreza Najafi Anaraki
Street address
Bushehr University of Medical Science
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dr Majid Asadi
Full name of responsible person
Dr.Abdolreza Najafi Anaraki
Street address
Bushehr University of Medical Sciences
City
Bushehr
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dr Majid Asadi
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty