

# 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 bupivacaine .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 bupivacaine .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

Bushehr University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 1354 0088

##### Email address

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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 Satisfaction

**Timepoint**

24 hours

**Method of measurement**

Question

**Intervention groups****1****Description**

In control group all patients receive 20 Milliliters per kilogram normal saline

**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**

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**City**

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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

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Dr. Abdolreza Najafi Anaraki

**Position**

Associate Professor

**Other areas of specialty/work**

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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*