

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of preemptive analgesia with intravenous administration of Apotel (paracetamol) & ketorolac on post operative pain relief following elective lower abdominal surgery

Protocol summary

Summary

Objectives: To compare the preemptive analgesia with intravenous administration of Apotel (paracetamol) & ketorolac on post-operative pain relief following elective lower abdominal surgery. Research Design: Conduction of a randomized, double-blind, clinical trial, method of randomization: simple randomization by computer. Major Inclusion Criteria; ASA I-II; patients undergoing elective lower abdomen surgeries. Major Exclusion Criteria; Opium addicted patients; drug allergy history; a history of gastrointestinal bleeding or kidney failure, lack of consent to participate in this study. Sample Size: 320 patients found eligible based on the inclusion criteria. Interventions: 320 patients in the both groups received either Paracetamol 15 mg / kg IV or Ketorolac 0.4 -0.6 mg / kg IV before the induction of anesthesia. The postoperative pain was evaluated by VAS index at 12,6,2,0 and 24 hours after surgery. In the recovery room (meperidine mg / kg 5/0 - 25/0) is used for analgesia. Finally, nausea and vomiting, shivering by (BSAS) Bedside Shivering Assessment Scale , the amount of drug consumption, intraoperative bleeding and the cost of hospitalization between the two groups were measured and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081723663N1**
Registration date: **2016-02-04, 1394/11/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-04, 1394/11/15

Registrant information

Name

Mehdi Feiz Dolatabadi

Name of organization / entity

Bandarabbas University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Bandar Abbas University of Medical Sciences

Expected recruitment start date

2016-01-24, 1394/11/04

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of preemptive analgesia with intravenous administration of Apotel (paracetamol) & ketorolac on post operative pain relief following elective lower abdominal surgery

Public title

Comparison of Apotel (paracetamol) & ketorolac on post operative pain relief following elective lower abdominal surgery

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion Criteria; ASA I-II; patients undergoing elective lower abdomen surgeries. Exclusion Criteria; Opium addicted patients; drug allergy history; a history of gastrointestinal bleeding or kidney failure; lack of consent to participate in this study

Age
From **9 years** old to **86 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **320**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Bandar Abbas University Of Medical Sciences

Street address
Shahid Mohamadi Hospital, Jomhori Eslami Blv

City
Bandar Abbas

Postal code

Approval date
2013-04-21, 1392/02/01

Ethics committee reference number
HEC-93-1-24-2

Health conditions studied

1

Description of health condition studied
lower abdomen surgeries

ICD-10 code
R10.3

ICD-10 code description
Pain localized to other parts of lower abdomen

Primary outcomes

1

Description
postoperative pain

Timepoint
At 0 ,2,6,24 hours after surgery

Method of measurement
(VAS) Visual Analogue Scale

2

Description
postoperative pain

Timepoint
At 0,6,12,24 hours after surgery

Method of measurement
(BSAS) Bedside Shivering Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description
Ketorolac 0.4 –0.6 mg / kg IV is administered for the first group before the induction of anesthesia.

Category
Treatment - Drugs

2

Description
Paracetamol 15 mg / kg IV is administered for the second group before induction of anesthesia.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Mohamadi Hospital

Full name of responsible person
Hashem Jarineshin

Street address
Shahid Mohamadi Hospital, Jomhori Eslami Blvd.

City
Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Bandar Abbas
University of Medical Sc

Full name of responsible person

Dr Abdolazim Nejati Zadeh

Street address

Vice Chancellor for Research , Shahid Mohammadi
Hospital, Jomhori Eslami BLV.

City

Bandar Abbas

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Bandar Abbas University of
Medical Sc

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

Bandarabbas University of Medical Sciences

Full name of responsible person

Mehdi Feiz Dolatabadi

Position

Physician, Anesthesiologist

Other areas of specialty/work

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Hashem Jarineshin

Position

Cardio-Anesthesiologist

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Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

MS in English Teaching

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