Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 –o.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
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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 –o.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.

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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

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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