Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of paracetamol and pethedine in reducing opioid consumption and pain scale in patients under gastrointestinal tract malignancies surgery.

Protocol summary

Summary

Background:This study evaluated the degree of postoperative analgesia effects of paracetamol in patients with gastrointestinal malignancy surgery and consumption of narcotics in ICU(intensive care of unit). Inclusion criteria: patients who candidates for GI Malignancy surgery and admitted in ICU. Exclusion criteria: A history of sensitivity to paracetamol, kidney disease(end stage), liver disease or more than two times increase in the liver enzymes. 60 patients between 30 to 81 years old with gastrointestinal malignancy that admitted in ICU after surgery. Patients are randomly divided into two group of thirty. Patients in first group received max one grams(1gr) intravenous. Paracetamol according to weight every six hours(4gr/24h). In second groups patients received pethedine 0.5mg/kg up to 50mg. In both group patients received a fixed dosage of 35 mg pethedine according to their needs. Visual analog scare and hemodynamic parameters, nausea and vomiting evaluated before receiving of each dosage. This data recorded for three days every patients. This study evaluated paracetamol effect in decrease of pethedine consumption.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207283305N4**
Registration date: **2017-08-14, 1396/05/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-14, 1396/05/23

Registrant information

Name

Ebrahim Alijanpour

Name of organization / entity

Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor Of Research Babol University Of Medical Sciences

Expected recruitment start date

2012-07-05, 1391/04/15

Expected recruitment end date

2013-04-20, 1392/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of paracetamol and pethedine in reducing opioid consumption and pain scale in patients under gastrointestinal tract malignancies surgery.

Public title

Effect of paracetamol in gastrointestinal cancer surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA class I-III; patient whom

candidates GI Malignancy surgery and are hospitalized in ICU ward after surgery. Exclusion criteria: A History of sensitivity to paracetamol; kidney disease (end stage); liver disease or more than two times increase in the liver enzymes; severe malnutrition or dehydration; alcohol users; Recipients Recipients probensid, Salyslamyd or drugs that are induce liver enzymes.Severe drop in blood pressure during or after, severe dyspnea requiring respiratory support, severe thrombocytopenia, decreased level of consciousness.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study was double blinded.At sampling time Patient and information collector were not aware of which group they would be and patients randomly divided in 2 groups, base on their folder numbers. The study designer was inform about drugs administration.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
Daneshgah Square, Ganjafrooz Avenue

City
Babol

Postal code

Approval date
2012-06-26, 1391/04/06

Ethics committee reference number
MUBABOL.REC.1391.6

Health conditions studied

1

Description of health condition studied
Gastrointestinal Malignancies

ICD-10 code
C16

ICD-10 code description
Malignant neoplasm of stomach

2

Description of health condition studied
Gastrointestinal Malignancies

ICD-10 code
C17

ICD-10 code description
Malignant neoplasm of small intestine

3

Description of health condition studied
Gastrointestinal Malignancies

ICD-10 code
C18

ICD-10 code description
Malignant neoplasm of colon

4

Description of health condition studied
Gastrointestinal Malignancies

ICD-10 code
C15

ICD-10 code description
Malignant neoplasm of oesophagus

Primary outcomes

1

Description
Reduce pain

Timepoint
Three days after surgery.

Method of measurement
VAS

Secondary outcomes

1

Description
Nausea & Vomiting

Timepoint
Three days after surgery

Method of measurement
Visual and questional

Intervention groups

1

Description
Intervention group: every 6 hours up to a maximum weight based on grams (total dose 24 h 4 grams) Paracetamol IV to receive. If a patient requires drug for pain or analgesic PRN 0.5mg/kg, up to a maximum ceiling of 35 mg to receive.
Category
Treatment - Drugs

2

Description
Control group: patients, 0.5mg/kg every 6 hours, up to a maximum of 50 mg analgesic receives and the need for additional drug fixed dose of 35 mg intravenously has analgesic.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr Ebrahim Alijanpour
Street address
Shahid Ghasemi Avenue
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor of Research Babol University of Medical Sciences
Full name of responsible person
Dr Aliakbar Moghadamnia
Street address
Vice-chancellor of Research, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor of Research Babol University of Medical Sciences
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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Person responsible for updating data

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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