

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 1228 0013

###### Email address

dralijanpour@mubabol.ac.ir

##### 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 questionnal

## 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**

Babol University of Medical Sciences

**Full name of responsible person**

Dr Ebrahim Alijanpour

**Position**

Associate Professor of Anesthesiology

**Other areas of specialty/work**

**Street address**

Anesthesiology Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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**Web page address**

**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

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**Web page address****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*