Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Evaluating the effect of intravenous Paracetamol or Diclofenac Sodium suppositories on the need for intravenous narcotic administration for pain relief in patients underwent gastrectomy

Protocol summary

Summary

Patients undergoing gastrectomy do experience sever pain after surgery. The study sample size included 88 patients (age range 40-70 years) with gastric cancer and no history of long-term use of opioids. The study will investigate the effect of adding two analgesic adjuvants for severe pain, including intravenous paracetamol and diclofenac sodium suppositories on pain management of patients with narcotic based therapy as Patient Controlled Analgesia (PCA). The main evaluation criteria include reduction in required dose of narcotics and pain intensity, and patient's satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112078322N1**
Registration date: **2012-06-02, 1391/03/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-06-02, 1391/03/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2012-06-04, 1391/03/15

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of intravenous Paracetamol or Diclofenac Sodium suppositories on the need for intravenous narcotic administration for pain relief in patients underwent gastrectomy

Public title

Evaluating the effect of intravenous Paracetamol or Diclofenac Sodium suppositories on the need for intravenous narcotic administration for pain relief in patients underwent stomach surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients with gastric cancer who are candidate for gastrectomy 2. Age range between 40 to70 years 3. Ability to understand PCA pump use Exclusion criteria: 1. History of allergy to morphine, acetaminophen, and diclofenac sodium 2. History of heart failure (EF<40%), kidney failure (C2>2), moderate to severe COPD 3. Weight over 10 kilograms or less than 50 kilograms 4. Long-term use of opioids before surgery (for more than 2 weeks continuously)

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ghoreyshi Building, Daneshgah Street

City

Mashhad

Postal code

Approval date

2012-02-18, 1390/11/29

Ethics committee reference number

900184

Health conditions studied

1

Description of health condition studied

Gastric surgery

ICD-10 code

Z90.3

ICD-10 code description

Acquired absence of part of stomach

Primary outcomes

1

Description

Pain intensity

Timepoint

Within the first 24 hours after intervention

Method of measurement

Verbal Analogue Scale

Secondary outcomes

1

Description

Level of Consciousness

Timepoint

Within the first 24 hours after intervention

Method of measurement

Richmond Agitation Sedation Scale (RASS)

2

Description

Oxygen saturation levels

Timepoint

Within the first 24 hours after intervention

Method of measurement

Pulse oximetry

3

Description

Respiratory rate

Timepoint

Within the first 24 hours after intervention

Method of measurement

Counting the number of breaths per minute

4

Description

Nausea

Timepoint

Within the first 24 hours after intervention

Method of measurement

Times of nausea and womiting

5

Description

Morphine consumption

Timepoint

Within the first 24 hours after intervention

Method of measurement

mg/day

Intervention groups

1

Description

Adding intravenous Paracetamol to Morphine PCA in MP group

Category

Treatment - Drugs

2

Description
Adding Diclofenac Sodium suppositories to Morphine PCA in MD group
Category
Treatment - Drugs

3

Description
Only Morphine PCA to control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Surgical Oncology Research Center
Full name of responsible person
Dr. Alireza Bameshki
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Sponsors / Funding sources

1

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Full name of responsible person
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Vice Chancellor for Research, Ghoreyshi Building, Daneshgah Street
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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

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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