

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Multimodal Preincisional Early Premedication to Prevent Pain After Cholecystectomy

Protocol summary

Summary

Background and Objectives: Postoperative pain after open cholecystectomy is one of the several factors that led to numerous complication and increases in mortality, morbidity. Multi-modal pre-emptive analgesia can help in controlling the pain via different mechanisms. This study intends to determine if this method could reduce post operative pain and complications as well as the amount of post operative analgesics requirements. Design: Sixty patients, who are candidate for open Cholecystectomy, will be recruited. Main inclusion criteria are patients under going open open Cholecystectomy and main exclusion criteria are history of addiction, hypochodriasis, and coagulation disorders. After providing written consent form, they will be randomly divided into the two groups: Study group will undergo four types of multi-modal pre-emptive analgesia (Diclofenac suppository 100 mg, Clonidine 0.2 mg half an hour before surgery, Ketamine 50 mg IV after induction of anaesthesia, infiltration of Bupivacaine 0.25% at the site of incision), while the control group will receive only one type of modality (infiltration of Bupivacaine 0.25% at the site of incision) plus placebo. At the end of the study two groups will be compared in terms of pain and analgesic consumption at various times after operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138712291772N2**

Registration date: **2010-05-31, 1389/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-31, 1389/03/10

Registrant information

Name

Dawood Aghamohammadi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1381 8940

Email address

aghamohammadid@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz medical university

Expected recruitment start date

2009-05-01, 1388/02/11

Expected recruitment end date

2010-01-01, 1388/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Multimodal Preincisional Early Premedication to Prevent Pain After Cholecystectomy

Public title

Post operative pain management

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: age from 20 to 60 people who are going to have open chlecystectomy; Exclusion criteria : Coagulopathy, Refuse to participate, Addiction, hypochonderiasis

Age

From **20 years** old to **60 years** old

Gender
Both

Phase
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
Used

Assignment
Parallel

Other design features
Impact on reducing opium use in the ward

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz medical university, reseach ethical committee

Street address

Tabriz medical university

City

Tabriz

Postal code

5167718113

Approval date

2009-03-29, 1388/01/09

Ethics committee reference number

5/4/174

Health conditions studied

1

Description of health condition studied

Cholecystitis and cholelithiasis

ICD-10 code

K80.1, K80

ICD-10 code description

Calculus of gallbladder with other cholecystitis and Other cholelithiasis

2

Description of health condition studied

opioid consumption

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

2, 4, 6, 12, 24, and 48 hours after operation

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Opioid consumption

Timepoint

2, 4, 6, 12, 24, and 48 hours after operation

Method of measurement

Total dose

Intervention groups

1

Description

Control group: instead of Diclofenac, Clonidine and Ketamine they received placebo before the operation, but the surgical site infiltrated with Bupivacaine 0.25% before incision

Category

Placebo

2

Description

Intervention group received Diclofenac suppository 100 mg, Clonidine 0.2 mg half an hour before surgery and Ketamine 50 mg IV after induction of anesthesia. Site of Incision were infiltrated before the incision with Bupivacaine 0.25%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital Tabriz medical University

Full name of responsible person

Dawood Aghamohammadi

Street address

Tabriz ,Imam Reza HHospital

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz medical university

Full name of responsible person

Dawood Aghamohammadi

Street address

Tabriz medical university

City

Tabriz

Grant name

طرح تحقیقاتی

Grant code / Reference number

88/2/12

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

Yes

Title of funding source

Tabriz medical university

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**

Anesthesiology Dept

Full name of responsible person

Dawood Aghamohammadi

Position

Assistant professor

Other areas of specialty/work**Street address**

Daneshgah Avenue

City

Tabriz

Postal code

5167718113

Phone

+98 41 1381 8940

Fax

+98 41 1381 8940

Email

aghamohammadid@tbzmed.ac.ir

Web page address

www.tbzmed.ac.ir

Person responsible for scientific

inquiries

Contact**Name of organization / entity**

Anesthesia Dept

Full name of responsible person

Dawood Aghamohammadi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Daneshgah avenue / Imam Reza Hospital

City

Tabriz

Postal code

5167718113

Phone

+98 41 1381 8940

Fax

+98 41 1381 8940

Email

aghamohammadid@tbzmed.ac.ir

Web page address

www.tbzmed.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Anesthesia Dept

Full name of responsible person

Dawood Aghamohammadi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Imam Reza Hospital / Tabriz medical university

City

Tabriz

Postal code

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Phone

+98 41 1381 8940

Fax

+98 41 1381 8940

Email

aghamohammadid@tbzemed.ac.ir

Web page address

www.tbzemed.ac.ir

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