Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

The Comparison of the effect of Ondansetron and Apotel on postoperative pain control in patients with upper limb fracture undergoing general anesthesia

Protocol summary

Summary

The Objectives of this study is to evaluate the effect of Endosome and Apotel on postoperative pain in patients with upper limb fracture undergoing general anesthesia. This is a phase III, single center, double-blind, randomized clinical trial in which patients with upper limb fractures referred to the Gorgan 5 Azar Medical Education Center will participate. They will be assigned into two intervention and control groups (sample size=50) through block randomization. Major eligibility criteria include: aged over 15 years, anesthesia risk factors 1 and 2, upper limb fracture. Primary exclusion criteria include patients with uncontrolled diabetes, patients with ischemic heart disease and stroke. After the end of the surgery and in the recovery phase, both groups will receive Patient Controlled Analgesia (PCA). For the control group, the pain pump will contain 2 grams of Apotel, which will be diluted with 100 cc normal saline 0.9 %. For the intervention group, the pain pump will contain 2 grams of Apotel and 8 milligrams of Ondansetron, which will be diluted with 100 cc normal saline 0.9 % and will be delivered at the rate of 4 cc / hr. The pain relief will be evaluated for 24 hours. The main outcome measure in this study will be pain and the main influencing variables will be the type of treatment group (intervention group, control group), gender, age, and smoking.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062133566N1**
Registration date: **2017-08-19, 1396/05/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-19, 1396/05/28

Registrant information

Name
Fatemeh Mehravar
Name of organization / entity
Golestan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 912 893 7199
Email address
f.mehravar@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Golestan University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the effect of Ondansetron and Apotel on postoperative pain control in patients with upper limb fracture undergoing general anesthesia

Public title

The effect of Ondansetron in combination with Apotel in

pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA Class 1; Upper limb fracture; Patients who undergo anesthesia with propofol as an anesthetic inducer; Satisfied to participate in the study; being at the age of 15 and older. Exclusion criteria: ASA grade 3 and 4; uncontrolled diabetes; history of ischemic heart disease (IHD); history of stroke; malignancy; psychiatric problems; Pregnancy; surgery duration greater than 120 minutes; history of substance abuse or drug abuse; Alcohol consumption; history of liver problems; history of Apotel (acetaminophen) sensitivity; history of nausea and vomiting after previous surgical procedure; Patients with long Q-T intervals.

Age

From **15 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Participants in the study by Block Randomization method will be allocated to intervention and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences.

Street address

Vice chancellor for research, Golestan University of Medical Sciences, Shast kolah Avenue

City

Gorgan

Postal code

49177-61551

Approval date

2017-07-23, 1396/05/01

Ethics committee reference number

IR.GOUMS.REC.1396.127

Health conditions studied

1

Description of health condition studied

Patients with upper limb fractures.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

24 hours and 48 hours after recovery.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the pain pump will contain 2 grams of Apotel and 8 milligrams of Ondansetron, which will be diluted with 100 cc normal saline 0.9 % and will be delivered at the rate of 4 cc / hr.

Category

Treatment - Drugs

2

Description

Control group:the pain pump will contain 2 grams of Apotel, which will be diluted with 100 cc normal saline 0.9 % and will be delivered at the rate of 4 cc / hr.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

5Azar Hospital

Full name of responsible person

Dr Salehe Akhoondi

Street address

Beside 5Azar Avenue, Azar 6th, 5Azar Hospital.

City

Gorgan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Golestan University of Medical Sciences
Full name of responsible person
Dr Mohsen Saeedi
Street address
Vice chancellor for research, Golestan University of Medical Sciences, Shast kolah Avenue
City
Gorgan
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, Golestan 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
Golestan University of Medical Sciences
Full name of responsible person
Dr Mohammadhosein Taziki
Position
MD, ENT
Other areas of specialty/work
Street address
Vice chancellor for research, Golestan University of Medical Sciences, Shast kolah Avenue
City
Gorgan
Postal code
Phone
+98 17 3242 1660
Fax
Email
dr.taziki@goums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Golestan University of Medical Sciences.
Full name of responsible person
Dr Seyed Babak Mojaver Aghili
Position
M.D
Other areas of specialty/work
Street address
5 Azar Hospital, next to Azar sheshom, 5 Azar Avenue, Gorgan
City
Gorgan
Postal code
Phone
+98 17 3235 4936
Fax
Email
salehe_akhoondi@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Golestan University of Medical Sciences
Full name of responsible person
Fatemeh Mehravar
Position
Faculty Member
Other areas of specialty/work
Street address
Vice chancellor for research, Golestan University of Medical Sciences, Shast kolah Avenue
City
Gorgan
Postal code
Phone
+98 17 3235 4936
Fax
Email
mehravar10261@yahoo.com
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