

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of the analgesic effect of intravenous fentanyl and acetaminophen in treatment of postoperative pain lower extremity orthopedic problems in patients referred to Poursina hospital during the year 1391

Protocol summary

Summary

The aim of the study: A comparison of the analgesic effect of intravenous fentanyl and acetaminophen in treatment of postoperative pain lower extremity orthopedic problems in patients referred to Poursina hospital during the year 1391 Study design: randomized, not blinding, no placebo-controlled, single-center.I Study population: Inclusion criteria: candidate male for interlock surgery in closed fracture of tibia and fibula without smashing or segmented Exclusion criteria: patients with severe respiratory, liver and kidney problems, increased intracranial pressure (High ICP), sensitivity to acetaminophen, surgical problems, anesthesia interventions and complications during surgery Sample size: 114 patients Study intervention/ interventions: injection of 500 microgram vial of fentanyl, which is being built by Abu Reyhan company, receiving 1500 micrograms of it over 24 hours. (has been made 250ml with normal saline) Intervention time: After the surgery the patient returned to the recovery unit Primary outcome : pain control

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122611898N1**
Registration date: **2013-02-14, 1391/11/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-14, 1391/11/26

Registrant information

Name

Ahmadreza Mirbolouk

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 2250

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ah.mirbolouk@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Guilan University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-03-21, 1392/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the analgesic effect of intravenous fentanyl and acetaminophen in treatment of postoperative pain lower extremity orthopedic problems in patients referred to Poursina hospital during the year 1391

Public title

Analgesic effect in treatment of pain after surgery

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: candidate male for Interlock surgery in closed fracture of tibia and fibula without smashing or Segmented Exclusion criteria: patients in the event of severe respiratory, liver and kidney problems, increased intracranial pressure (High ICP), sensitivity to acetaminophen, surgical problems, anesthesia interventions and complications during surgery

Age
 From **25 years** old to **50 years** old

Gender
 Male

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **114**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

Namjoo Street, facing Azodi Stadium, headquarters of Guilan University of Medical Sciences

City

Rasht

Postal code

Approval date

2012-11-17, 1391/08/27

Ethics committee reference number

9110264805

Health conditions studied

1

Description of health condition studied

pain control

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

pain

Timepoint

After receiving drug at intervals 15.30, 45 minutes, 1, 2, 3, 4 and 5 hours

Method of measurement

Are examined through the pain score

Secondary outcomes

empty

Intervention groups

1

Description

1_ In persons who receiving the apotel, 1 gr of the drug (1000 mgr in a vial) in 150ml saline solution and per 6 hours, infusion 1 mgr of the drug during 15 minutes are administered.

Category

Treatment - Drugs

2

Description

2_ Those receiving 500 microgram vial of fentanyl, which is being built by Abu Reyhan company, 1500 micrograms over 24 hours of receiving it. (has been made 250 ml with normal saline)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

Mohammad Haghighi (MD)

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Department, Guilan University of Medical Sciences

Full name of responsible person

Rasoul Tabari (MD)

Street address

, ,Research and Technology Department, Guilan University of Medical Sciences, opposite of agriculture bank, Gas _ circle

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research and Technology Department, Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi (MD)

Position

Anesthesiologist /Associate of Guilan University of Medical Sciences

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

Poursina Hospital, Higher than the Census Bureau, Poursina intersection

City

Rasht

Postal code**Phone**

+98 13 1322 0306

Fax**Email**

manesthesist@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi (MD)

Position

Anesthesiologist/Associate of guilan university of medical sciences

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

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City

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Postal code**Phone**

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Fax**Email**

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Zinat Akbari

Position

Medical Student /participant

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

Rasht

Postal code**Phone****Fax****Email****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