

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of morphine and Buprenorphin in acute pain management in patients with acute abdomen

Protocol summary

Summary

The aim of the present study was to determine the efficacy of sub lingual Buprenorphin versus morphine injection in acute pain management and severity of withdrawal syndrome in addicted patients with acute abdomen. In a single-blind, Randomized study, 68 addicted patients undergoing laparotomy will be randomized to receive either 0.4 mg of sub lingual buprenorphine or 5 mg of intravenous morphine four times/day. The patients will be monitored for postoperative pain based on visual analog scale (VAS) and severity of withdrawal syndrome based on COWS in a period of 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080117811N5**
Registration date: **2014-08-08, 1393/05/17**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-08, 1393/05/17

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Office of Vice Chancellor for Research

Expected recruitment start date

2013-05-10, 1392/02/20

Expected recruitment end date

2014-06-10, 1393/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of morphine and Buprenorphin in acute pain management in patients with acute abdomen

Public title

Buprenorphin and pain

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: continuous use of opiate in last 10 days ; acute pain due to acute abdomen ; indication of use of narcotics ; Patients of American Society of Anesthesiologists (ASA) physical status I ; age 20-60
exclusion criteria: age less than 20 or more than 60 ; paracetamol prescription during last hour ; narcotics overdose ; undiagnosed acute abdomen ; multiple biliary duct stone ; loss of consciousness due to head trauma ; shock ; underlying disease effects on pain ; SBP<100 ; multi drug dependants

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: 68

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of medical science

Street address

Arak University of medical science,sardasht,arak,iran

City

Arak

Postal code

Approval date

2013-02-01, 1391/11/13

Ethics committee reference number

91-142-6

Health conditions studied

1

Description of health condition studied

acute abdominal pain

ICD-10 code

R10.0

ICD-10 code description

Severe abdominal pain (generalized)(localized)(with abdominal rigidity)

2

Description of health condition studied

opiate dependent patients

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

pain severity

Timepoint

hour 1 , 6 and 24 after surgery

Method of measurement

visual analog scale (VAS)

2

Description

withdrawal severity

Timepoint

hour 1 , 6 and 24 after surgery

Method of measurement

Clinical Opiates Withdrawal Scale(COWS)

Secondary outcomes

empty

Intervention groups

1

Description

0.4 mg of sub lingual buprenorphinee 4 times/day

Category

Treatment - Drugs

2

Description

5 mg of intravenous morphine 4 times/day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr.Solhi

Street address

Valiasr hospital , Arak , Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Science,Office of Vice Chancellor for Research

Full name of responsible person
 Mohammad Rafii
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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
 Arak University of Medical Science,Office of Vice
 Chancellor for Research
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