

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Compare intra pritoneal Bupivacine and Petedin with intravenous analgesics to prevent post operation

Protocol summary

Summary

For this reason we decided to compare intrapritoneal bupivacine and mepridine with intravenous analgesics to prevent post operation pain. This study is interventional clinical trial. 90 patient with symptomatic gallstones were divided in to 3 equal groups. In the first group we injected 40 ml of 0.25 % bupivacaine intrapritoneally. The second group received 25 mg of Petedin diluted in 40 ml normal saline interapretoneally. The third group treated with interavenous analgesics. Inclusion criteria: 20-75 years, gall stone without symptom, no history of heart disease, lung and kidney, impassibility Bupivacine and Petedin. Exclusion criteria: Gallstones complicated, allergy to bupivacine, Heart failure class 3 and 4, end stage renal disease, Open cholecystectomy ,addiction. Post operation pain was assessed with visual analogue scale at 0 , 6, 12 and 24 hours after sugery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030120258N3**

Registration date: **2016-03-07, 1394/12/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-07, 1394/12/17

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences and Health Services

Expected recruitment start date

2013-03-21, 1392/01/01

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

Compare intra pritoneal Bupivacine and Petedin with intravenous analgesics to prevent post operation

Public title

Compare intra pritoneal Bupivacine and Petedin with intravenous analgesics to prevent post operation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20-75 years; gall stone without symptom; no history of heart disease; lung and kidney; impassibility Bupivacine and Petedin Exclusion criteria: Gallstones complicated; allergy to bupivacine; Heart failure class 3 and 4; end stage renal disease; Open cholecystectomy ;addiction

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple 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 Sciences

Street address

Arak, Sardasht, Basij Square, Payambar Azam Complex, Reaserch Center

City

Arak

Postal code

848176941

Approval date

2012-09-03, 1391/06/13

Ethics committee reference number

91-132-7

Health conditions studied**1****Description of health condition studied**

cholecystectomy

ICD-10 code

k81.0

ICD-10 code description

Acute cholecystitis

Primary outcomes**1****Description**

Pain

Timepoint

after operation,6 hours after operation,12hours after operation,24 hours after operation

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Nausa and vomitting

Timepoint

after operation,6 and 12 and 24 hours after operation

Method of measurement

Observation

Intervention groups**1****Description**

first group intervention we injected 40 ml of 0.25 % bupivacaine intrapritoneally

Category

Treatment - Drugs

2**Description**

Second group intervention received 25 mg of Petedin diluted in 40 ml normal saline interapretoneally

Category

Treatment - Drugs

3**Description**

Third group treated with interavenous analgesics.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr Hospital

Full name of responsible person

Dr Shahin Fateh

Street address

Arak, Valiasr Hospital

City

Arak

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Rafiee

Street address

Arak, Sardasht, Basij Square, Payambar Azam
Complex, Reaserch Center

City

Arak

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 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**

Valiasr Hospital

Full name of responsible person

Dr Shahin fateh

Position

Professor of Thorax

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

Valiasr Hospital

City

Arak

Postal code

3814957558

Phone

+98 86 3222 2003

Fax**Email**

dr.norouziAzrzkmu.ac.ir

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

Medicine Department

Full name of responsible person

Dr Shahin Fateh

Position

Professor of Thorax

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

Reaserch Center, Payambar Azam Complex, Basij
Square, , Sardasht,Arak

City

Arak

Postal code

3814957558

Phone

+98 86 3222 2003

Fax**Email**

dr.norouzi@arakmu.ac.ir

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

Valiasr Hospital

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Square, , Sardasht,Arak

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+98 86 3222 2003

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