

# 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

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dr.norouzi@arakmu.ac.ir

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

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**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*