

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Comparison the effect of Paracetamol and Morphine with IV-PCA in control of postop pain in Cholecystectomy

#### Protocol summary

##### Summary

The aim of this study was the comparison of the analgesic effect of morphine and paracetamol in the patients undergoing Cholecystectomy , using IV-PCA method Seventy patients who had undergone Cholecystectomy were studied using double blind randomized clinical trial (35 patients in both groups) in the Shahid Rajaei Center and Velayat Hospital. Inclusion criteria include: ASA 1 and 2 patients 15 to 65 years who were undergoing Cholecystectomy Operation takes less than 2.5 hours. Exclusion criteria include: People using opioids, painkillers and sedatives regularly and in large doses and patients with a history of lung or liver problems. The parameters of the severity of pain and nausea (VAS), hemodynamic changes (BP , HR), pruritus, o2 saturation and patient satisfaction (VAS) of both groups were measured by a trained colleague.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013012712298N1**

Registration date: **2013-05-19, 1392/02/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-05-19, 1392/02/29

##### Registrant information

###### Name

Reza Pourfallah

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3272 0831

##### Email address

rpoorfallah@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Qazvin University of Medical Sciences

##### Expected recruitment start date

2010-08-01, 1389/05/10

##### Expected recruitment end date

2011-08-01, 1390/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of Paracetamol and Morphine with IV-PCA in control of postop pain in Cholecystectomy

##### Public title

Effect of Paracetamol on Postop Pain

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria :patients with ASA 1 and 2 ; 15 to 65 years ; who were undergoing Cholecystectomy Operation ; takes less than 2.5 hours. Exclusion criteria : People using opioids, painkillers and sedatives regularly and in large doses ; patients with a history of lung problems ; patients with a history of liver problems

##### Age

From **15 years** old to **65 years** old

##### Gender

Both

##### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 70

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Qazvin University of Medical Sciences

##### Street address

Qazvin University of Medical Sciences, Bahonar  
bolivar, Qazvin

##### City

Qazvin

##### Postal code

34185-745

##### Approval date

2012-06-25, 1391/04/05

##### Ethics committee reference number

28-20-6031

## Health conditions studied

### 1

#### Description of health condition studied

Cholecystectomy

#### ICD-10 code

Z90.4

#### ICD-10 code description

Acquired absence of other parts of digestive tract

## Primary outcomes

### 1

#### Description

Post Operative Pain

#### Timepoint

2, 4, 6 and 8 Hours after Intervention

#### Method of measurement

VAS

## Secondary outcomes

### 1

#### Description

Nausea

#### Timepoint

2, 4, 6 And 8 Hours After Intervention

#### Method of measurement

VAS

### 2

#### Description

Satisfaction

#### Timepoint

2, 4, 6 and 8 Hours after Intervention

#### Method of measurement

VAS

### 3

#### Description

Pruritus

#### Timepoint

2, 4, 6 and 8 Hours after Intervention

#### Method of measurement

Yes or no

### 4

#### Description

Arterial Oxygen Desaturation

#### Timepoint

2, 4, 6 and 8 Hours after Intervention

#### Method of measurement

Yes or no

### 5

#### Description

Changes in Blood Pressure

#### Timepoint

2, 4, 6 and 8 Hours after Intervention

#### Method of measurement

Into three groups: Low, Medium and High

### 6

#### Description

Changes in Heart rate

#### Timepoint

2, 4, 6 and 8 Hours after Intervention

#### Method of measurement

Into three groups: low, medium and high

## Intervention groups

### 1

#### Description

Paracetamol. Controlling pain after laparotomy surgery  
(Cholecystectomy). with maximum dose 125 mg per hour

with intravenous PCA. Lasting 8 hours after surgery

### Category

Treatment - Drugs

## 2

### Description

Morphine. Controlling pain after laparotomy surgery (cholecystectomy). with maximum dose 20.0 mg per kg in hour with intravenous PCA. Lasting 8 hours after surgery

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shahid Rajaii Hospital

#### Full name of responsible person

Reza Pourfallah

#### Street address

No 88, khalag Ave, shahid fahmideh Sq

#### City

Karaj

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Qazvin University Of Medical Sciences

#### Full name of responsible person

Reza Pourfallah

#### Street address

No88, khalaj Ave, shahid fahmide Sq

#### City

Karaj

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

#### Full name of responsible person

Reza Pourfallah

#### Position

Resident of anesthesiology

#### Other areas of specialty/work

#### Street address

No88, khalaj Ave, shahid fahmide Sq

#### City

Karaj

#### Postal code

#### Phone

+98 26 3272 0831

#### Fax

#### Email

rpoorfallah@qums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Qazvin University of Medical Sciences

#### Full name of responsible person

Siamak Yaqubi

#### Position

Intensivist

#### Other areas of specialty/work

#### Street address

Shahid Rajaii Hospital

#### City

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#### Postal code

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+98 26 3272 0831

#### Fax

#### Email

siamak yaqubi@yahoo.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Qazvin University of Medical Sciences

#### Full name of responsible person

Reza Oourfallah

#### Position

Resident of Anesthesiology

#### 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**

rpoorfallah@qums.ac.ir

**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*