

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effect of single dose intravenous dexamethasone on post-operative pain in patients undergoing laparoscopic cholecystectomy in Razi hospital during 2012

#### Protocol summary

##### Summary

This double blind randomized clinical trial will be carried out on 122 patients who are admitted in Razi hospital and are candidates of laparoscopic cholecystectomy in order to assess the effect of single dose intravenous dexamethasone on post-operative pain in this kind of surgery. Inclusion criteria consist of patients aged between 18 to 60 years old, while the exclusion criteria are renal failure, hepatic failure, history of gastric/duodenal ulcers, sensitivity to glucocorticoid(s), and those under treatment with glucocorticoids and/or immunosuppressive agents. The sample will be divided into two groups of 61 patients. Each patient in the case group will receive 8 mg single dose intravenous dexamethasone during induction of anesthesia while patients of control group will receive normal saline as placebo at the same time. The severity of post-operative pain will be assessed in both groups in recovery, and 2, 6, 12 and 24 hours post-operatively, and will be compared to each other statistically.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012072810424N1**

Registration date: **2013-02-27, 1391/12/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-02-27, 1391/12/09

##### Registrant information

###### Name

Babak Masoudrad

##### Name of organization / entity

Jondishapour University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1336 7543

##### Email address

masoudrad.b@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Jondishapour University of Medical Sciences

##### Expected recruitment start date

2012-05-21, 1391/03/01

##### Expected recruitment end date

2012-08-21, 1391/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of single dose intravenous dexamethasone on post-operative pain in patients undergoing laparoscopic cholecystectomy in Razi hospital during 2012

##### Public title

Effect of dexamethasone on post-operative pain in laparoscopic cholecystectomy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Candidates of laparoscopic cholecystectomy that are 18 to 60 years old. Exclusion criteria: Patients younger than 18 or elder than 60 years

old; Renal failure; Hepatic failure; History of gastric/duodenal ulcers; Sensitivity to glucocorticoid(s); Those under treatment with glucocorticoids and/or immunosuppressive agents.

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **122**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

### 1

#### Registry name

N/A

#### Secondary trial Id

N/A

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Jondishapour University of Medical Sciences

##### Street address

Golestan Boulevard

##### City

Ahvaz

##### Postal code

#### Approval date

2012-05-19, 1391/02/30

#### Ethics committee reference number

eth-468

## Health conditions studied

### 1

#### Description of health condition studied

cholecystitis

#### ICD-10 code

K81.9

#### ICD-10 code description

Cholecystitis, unspecified

## Primary outcomes

### 1

#### Description

Post-operative pain

#### Timepoint

In recovery, 2 hours post-op, 6 hours post-op, 12 hours post-op, 24 hours post-op

#### Method of measurement

Visual Analogue Scale (VAS)

## Secondary outcomes

### 1

#### Description

N/A

#### Timepoint

N/A

#### Method of measurement

N/A

## Intervention groups

### 1

#### Description

Case group: Intravenous administration of 8 mg single dose dexamethasone during induction of anesthesia.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Intravenous administration of 2 ml of normal saline during induction of anesthesia

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi Hospital

##### Full name of responsible person

Babak Masoudrad

##### Street address

Razi Hospital, Palestine Boulevard

##### City

Ahvaz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Jondishapour University of Medical Sciences

**Full name of responsible person**

Dr. Mostafa Feqhi

**Street address**

Vice chancellor for research, Jondishapour University of Medical Sciences

**City**

Ahvaz

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

Yes

**Title of funding source**

Vice chancellor for research, Jondishapour 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**

Jondishapour University of Medical Sciences

**Full name of responsible person**

Dr. Babak Masoudrad

**Position**

Anesthesiology Resident

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Dr. Ahmad Reza Mohtadi

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## Person responsible for updating data

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Imam Khomeini Hospital

**City**

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**Postal code****Phone**

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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*