

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Diclofenac suppository on pain control in post laparoscopic cholecystectomy

#### Protocol summary

##### Summary

To determine the effect of Diclofenac suppositories in postoperative pain control, in removal of gallbladder. In a double-blind method, 60 patients with gallstones (which have no acute inflammation) are divided randomly into two groups . For first group diclofenac suppository is placed after Anesthesia and after recovery. In another group placebo is used. Postoperative pain is measured by Visual Analysis scale and the drug dose is calculated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201009083384N4**

Registration date: **2011-02-21, 1389/12/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-02-21, 1389/12/02

##### Registrant information

##### Name

Ameneh Ebrahim Valoojerdi

##### Name of organization / entity

Endocrine research center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8894 5247

##### Email address

info@lapsurg.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2010-10-23, 1389/08/01

##### Expected recruitment end date

2011-02-20, 1389/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Diclofenac suppository on pain control in post laparoscopic cholecystectomy

##### Public title

Effect of Diclofenac suppository on pain control in post laparoscopic cholecystectomy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria : Gallstone patients who referred to Rasoul Akram hospital Exclusion Criteria: Acute backpack cystic , change intraoperative anesthetic protocol, having pain before surgery, pregnancy and breastfeeding, asthma or a known history of asthma, coagulopathy, history of upper or lower gastrointestinal bleeding during the past year, liver or kidney failure, history of sensitivity to NSAIDs , performed simultaneously with other gallbladder surgery, addiction to opiates or painkillers, duration of surgery more than 90 minutes

##### Age

No age limit

##### Gender

Both

##### Phase

3

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences , Hemat highway

**City**

Tehran

**Postal code**

**Approval date**

2010-06-27, 1389/04/06

**Ethics committee reference number**

890

**Health conditions studied**

1

**Description of health condition studied**

Diclofenac suppository on pain control in post laparoscopic cholecystectomy

**ICD-10 code**

K80-K87

**ICD-10 code description**

Disorders of gallbladder, biliary tract and pancreas

**Primary outcomes**

1

**Description**

Pain

**Timepoint**

Immediately after anesthesia - three hours later

**Method of measurement**

Visual Analysis Scale

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention: Diclofenac suppository (100 mg) immediately after anesthesia and in three hours after recovery.

**Category**

Treatment - Drugs

2

**Description**

Control: placebo

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Rasoul Akram Hospital

**Full name of responsible person**

**Street address**

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr.Maziar Moradi

**Street address**

Iranian university of Medical sciences , Hemat highway

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Hossein saeidi motahar

**Position**

General surgeon

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## Person responsible for updating data

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**Position****Other areas of specialty/work****Street address****City****Postal code****Phone****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*

## Person responsible for scientific inquiries

### Contact

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Iran University of Medical Sciences

**Full name of responsible person**

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General surgeon

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