

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of celecoxib and ibuprofen versus placebo on pain after laparotomy in drug dependence: a double-blind randomized clinical trial

#### Protocol summary

##### Summary

Objectives: To assess the effect of celecoxib and ibuprofen versus placebo on pain after laparotomy in drug dependence. Design: a double blind randomized clinical trial. Setting and conduct: The eligible drug dependence who are candidate for laparotomy and will refer to Beasat Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) age of 18 to 60 years; (b) candidate for laparotomy; (c) drug dependence. Exclusion criteria: (a) using analgesic during 8 hours before surgery; (b) during pregnancy of breastfeeding; (c) sensitivity to celecoxib, ibuprofen, or vitamin B; (d) affected with cardiovascular diseases, renal diseases, liver diseases, and gastrointestinal diseases; (e) alcohol abuse. Intervention: (a) 200 mg oral celecoxib single dose 1 hour before surgery; (b) 400 mg oral ibuprofen single dose 1 hour before surgery. Control: one tablet vitamin B single dose 1 hour before surgery. Primary outcome: measuring the pain severity 1 and 6 hours after surgery using VAS scale. Secondary outcome: number of narcotic or analgesic used during the 6 hours after surgery by checking medical record.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201411269014N50**

Registration date: **2014-12-02, 1393/09/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-12-02, 1393/09/11

##### Registrant information

**Name**

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research the Technology, Hamadan  
University of Medical Sciences

##### Expected recruitment start date

2013-09-23, 1392/07/01

##### Expected recruitment end date

2014-09-21, 1393/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of celecoxib and ibuprofen versus placebo on pain after laparotomy in drug dependence: a double-blind randomized clinical trial

##### Public title

Effect of celecoxib and ibuprofen versus placebo on pain after laparotomy in drug dependence

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 18 to 60 years; (b) candidate for laparotomy; (c) drug dependence. Exclusion criteria: (a) using analgesic during 8 hours before surgery; (b)

during pregnancy of breastfeeding; (c) sensitivity to celecoxib, ibuprofen, or vitamin B; (d) affected with cardiovascular diseases, renal diseases, liver diseases, and gastrointestinal diseases; (e) alcohol abuse.

#### Age

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

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **114**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

Randomization: random assignment of the patients systematically one at a time to intervention and control groups. Blinding: drugs have no label thus patients will not be aware of the type of treatment they receive. In addition, the examiner who will examine the patients is another person that will not be aware of the type of intervention. Therefore, the trial will be run as double blinded.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor of Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

##### Postal code

6517838695

#### Approval date

2014-05-14, 1393/02/24

#### Ethics committee reference number

D/P/16/35/9/87

## Health conditions studied

### 1

#### Description of health condition studied

Pain

#### ICD-10 code

R52

#### ICD-10 code description

Unspecified pain

## Primary outcomes

### 1

#### Description

measuring the pain severity

#### Timepoint

1 and 6 hours after surgery

#### Method of measurement

using VAS scale

## Secondary outcomes

### 1

#### Description

number of narcotic or analgesic used

#### Timepoint

during the 6 hours after surgery

#### Method of measurement

by checking medical record.

## Intervention groups

### 1

#### Description

200 mg oral celecoxib single dose 1 hour before surgery

#### Category

Treatment - Drugs

### 2

#### Description

400 mg oral ibuprofen single dose 1 hour before surgery

#### Category

Treatment - Drugs

### 3

#### Description

one tablet of vitamin B single dose 1 hour before surgery

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Beasat hospital

##### Full name of responsible person

Elham Khorshidi  
**Street address**  
Beasat hospital, Shahed Ave.  
**City**  
Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**  
Dr Saeid Bashirian

**Street address**  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**  
Hamadan

#### 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 the Technology, Hamadan  
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**  
Elham Khorshidi

**Full name of responsible person**  
Elham Khorshidi

**Position**  
Medical student

**Other areas of specialty/work**

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Beasat hospital, Shahed Ave.

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Hamadan  
**Postal code**  
**Phone**  
+98 81 8264 0020

#### Fax

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elhamkhorshidi1368@gmail.com

#### Web page address

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Beasat hospital

**Full name of responsible person**  
Dr Afshin Farahanchi

**Position**  
Anesthesiologist

**Other areas of specialty/work**

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Beasat hospital, Shahed Ave.

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afarhanchi1970@yahoo.com

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## Person responsible for updating data

#### Contact

## 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*