Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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

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Name of organization / entity

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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.
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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
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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

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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