Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of diclofenac and acetaminophen combined with patient controlled analgesia, in the managment of pain after laminectomy surgery.

Protocol summary

Summary

We are going to compare the effects of diclofenac suppository and intravenous acetaminophen combined with patient controlled analgesia, in the management of pain after laminectomy surgery in this study. 100 patients aged between 18-65 years candidate for lumbar laminectomy surgery, with no history of cardiac, renal or hepatic disease who had signed the informed consent form, will be randomly selected and evaluated in two (acetaminophen or diclofenac) groups. All patients receive intravenous patient controlled analgesia via a pump containing fentanyl 10 µg/ml with continuous infusion of 2 milliliters per hour and bolus infusion of 0.5 ml and lock out interval of 15 minutes. Patients in diclofenac and acetaminophen groups will receive 100 mg diclofenac or placebo suppository respectively before induction of anesthesia and the second dose this will be administrated 12 hours after surgery. Induction and maintenance of anesthesia are the same in two study groups. Intravenous infusion of 1 gram acetaminophen in 100 milliliters normal saline will be started 15 minutes before the end of surgery and 12 hours later in acetaminophen group and the other group will receive normal saline at the same time. In the case of sedation score above 3, IV PCA will be hold and patient will be monitored. In the case of pain score above 4, morphin four miligrams IV will be injected and recorded in the questionare. Pain score, sedation score, patient satisfaction, side effects like nausea and vomiting and total dose of injrcted opioid will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311168768N3**

Registration date: **2013-12-20, 1392/09/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-20, 1392/09/29

Registrant information

Name

Mahshid Nikooseresht

Name of organization / entity

Hamadan university of Medical Sciences, Faculty of Medicine

Country

Iran (Islamic Republic of)

Phone

+98 81 3823 5383

Email address

nikooseresht@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of diclofenac and acetaminophen combined with patient controlled analgesia, in the managment of pain after laminectomy surgery.

Public title
Comparison of diclofenac and acetaminophen in the managment of pain after back surgery.
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria: Patients candidate for laminectomy with American Society of Anesthesiologists (ASA) class I, II Exclusion criteria: Patients with Coagulation disorders, seizure, Asthma, renal or hepatic disease, addiction to opioids or alchohol, sensitivity to NSAIDS or acetaminophen, peptic ulcer disease, opium or NSAIDs use in recent 24 hr, surgery time more than 150 minutes and patient refusal
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
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
Committee of Ethics in Research, Hamadan University of Medical Sciences
Street address
Hamadan University of Medical Science, Shahid Fahmideh Street, Hamadan
City
Hamadan
Postal code
65178
Approval date
2013-10-21, 1392/07/29
Ethics committee reference number
16/35/9/2418/پ

Health conditions studied

1

Description of health condition studied
acute postoperative pain
ICD-10 code
R52.0A
ICD-10 code description
Acute pain

Primary outcomes

1

Description
Pain score
Timepoint
In recovery, 6 hours after surgery, 12 hours after surgery, 24 hours after surgery
Method of measurement
Visual Analogue Scale

2

Description
Total dose of narcotic used in patient controlled analgesia
Timepoint
24 hours after surgery
Method of measurement
Observation of PCA pomp and calculating the used narcotic by microgram

3

Description
Patient satisfaction
Timepoint
24 hours after surgery
Method of measurement
Questionare

4

Description
Total dose of Adjuvant analgesic
Timepoint
24 hours after surgery
Method of measurement
With questionare and by miligram

Secondary outcomes

1

Description
Nausea and vomiting
Timepoint
In recovery, 6 hours after surgery, 12 hours after

surgery, 24 hours after surgery

Method of measurement

Questionare

2

Description

Sedation score

Timepoint

At the end of the surgery, after 24 hours

Method of measurement

By using Ramsy sedation scale

Intervention groups

1

Description

Intervention group: Diclofenac suupp 100mg immediately before induction of anesthesia and 12 hours after surgery, infusion of 100 cc normal saline 15 minutes before the end of the surgery and 12 hours after surgery. In recovery an intravenous patient controlled analgesia (IV PCA) pump containing 100 cc normal saline and 20 cc fentanyl (1000µg) will be connected. The pump characteristics: 2 cc continous flow and bolus of 0.5 cc with lockout interval of 15 minutes. In the case of sedation score above 3, IV PCA will be hold and patient will be monitored. In the case of pain score above 4, morphin four miligrams IV will be injected and recorded in the questionare.

Category

Treatment - Drugs

2

Description

Control group: will recieve placebo suppository immediately before induction of anesthesia and 12 hours after surgery, infusion of 1 gram intravenous acetaminophen in 100 cc normal saline 15 minutes before the end of the surgery and 12 hours after surgery. In recovery an intravenous patient controlled analgesia(IV PCA) pump containing 100 cc normal saline and 20 cc fentanyl (1000µg) will be connected. The pump characteristics: 2 cc continous flow and bolus of 0.5 cc with lockout interval of 15 minutes. In the case of sedation score above 3 IV PCA will be hold and patient will be monitored. In the case of pain score above 4, morphin 4 miligrams IV will be injected and recorded in the questionare.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beast Hospital

Full name of responsible person

Mahshid Nikooseresht

Street address

Anesthesiolgy Department, Besat hospital, ,Shahid Motahari Blvd, Resalat Square, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology, Hamadan University Of Medical Sciences

Full name of responsible person

Saiid Bashirian

Street address

Hamadan University of Medical Science, Shahid Fahmideh Street, Hamadan

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 and 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

Hamadan University of Medical Sciences

Full name of responsible person

Mahshid Nkooseresht M.D

Position

Assistant Professor of Anesthsiology, Fellowship of Pain managenent

Other areas of specialty/work

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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