Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Evaluating the effect of preoperative sublingual buprenorphine on pain intensity after lumbar disc surgery

Protocol summary

Study aim
Evaluating the effect of preoperative sublingual buprenorphine on pain intensity after lumbar disc surgery

Design
This study was done as clinical trial (phase 3) with control group and parallel groups, double-blind, randomized (random allocation software), on 78 patients.

Settings and conduct
The study was performed on patients who were candidates for elective dissectomy at Imam Khomeini Hospital in Sari. Patients were randomly divided into two groups. Patients in the buprenorphine group received one buprenorphine tablet of 2 mg sublingually and patients in the placebo group received one placebo one hour before surgery sublingually. Pain severity, nausea and vomiting and the amount of drugs used by patients in the two study groups were evaluated and recorded after recovery in consciousness and then in the ward ... and at times 2, 4, 6, 12, 24 hours after surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria included: candidate for non-emergency lumbar disk surgery; age between 35 to 70 years old; no history of bupernorphine hypersensitivity. Exclusion criteria: patient's unwillingness at any time to continue the study; opioids use 24 hours prior to intervention; alcohol or drug abuse; incidence of any uncommon side effects during surgery.

Intervention groups
Patients in group A received a singlesubingual 2 mg Bupernorphine tablet (manufactured by Jalinous pharmaceutical company) and patients in group B received an oral placebo one hour before surgery

Main outcome variables
Opium usage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201026049147N1**
Registration date: **2020-12-09, 1399/09/19**
Registration timing: **retrospective**

Last update: **2020-12-09, 1399/09/19**
Update count: **0**

Registration date
2020-12-09, 1399/09/19

Registrant information

Name
Hojat Deilami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3332 8456

Email address
hojatdeilami@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
2018-03-21, 1397/01/01

Actual recruitment end date
2019-03-21, 1398/01/01

Trial completion date
2019-04-04, 1398/01/15

Scientific title
Evaluating the effect of preoperative sublingual buprenorphine on pain intensity after lumbar disc surgery

Public title
Effect of buprenorphine on pain intensity after surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient candidate for elective discectomy with 1 or 2 lumbar discs With ASA class I and II Age range 35-70 Conscious consent to participate in the study Hypersensitivity to buprenorphine Confirmation of diagnosis by physical examination, CT scan and MRI Patient's willingness to participate in the study and obtaining informed consent
Exclusion criteria:
Patient's unwillingness at any time to continue the study Incidence of any uncommon side effects during surgery. Alcohol or drug abuse Opioids use 24 hours prior to intervention Involvement of more than two lumbar disc
Age
From **35 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **78**
Actual sample size reached: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were divided into intervention and placebo groups by blocking method. Random numbers were generated for blocks with random allocation software. Samples were assigned in 11 blocks of 7 based on randomly generated numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
The blinding of the study is done in such a way that the drug is given to the patient in advance by the ward nurse, which is prepared based on block randomization and the patient group. Patient and the researcher unaware about the grouping.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Amir Mazandarani St.
City
Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2018-06-27, 1397/04/06
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1397.007

Health conditions studied

1

Description of health condition studied
Post-operative pain
ICD-10 code
G89.22
ICD-10 code description
Chronic post-thoracotomy pain

Primary outcomes

1

Description
Opium usage
Timepoint
0, 2, 4, 6, 12, 24 hours after surgery
Method of measurement
Checklist

Secondary outcomes

1

Description
Pain severity
Timepoint
0, 2, 4, 6, 12, 24 hours after surery
Method of measurement
Visual analogue scale

Intervention groups

1

Description
Intervention group: Received a single sublingual 2 mg Bupernorphine tablet (manufactured by Jalinous pharmaceutical company) one hour before surgery.
Category
Treatment - Drugs

2

Description
Control group: Received placebo sublingual one hour before surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeyni hospital
Full name of responsible person
Hojat Deilami
Street address
Imam khomeini hospital, Amir Mazandari street
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3331 1111
Email
hojatdeilami@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Majid Saeedi
Street address
Mazandaran University of Medical Sciences, Valiasr Blvd.
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3331 1111
Email
majsaeedi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Hojat Deilami
Position
Non-faculty specialist physician
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Imam khomeini hospital, Amir Mazandari street
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3331 1111
Email
hojatdeilami@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Farshad Hasanzadeh Kiabi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Imam khomeini hospital, Amir Mazandari street
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3331 1111
Email
Fhasanzadehk@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Hojat Deilami

Position
Non-faculty specialist physician

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Imam khomeini hospital, Amir Mazandari street

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Mazandaran

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4815733971

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+98 11 3331 1111

Email
hojatdeilami@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available