Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of preoperative melatonin on pain intensity after lumbar disc surgery

Protocol summary

Study aim
Determining the Effect of preoperative Melatonin on the Severity of Postoperative pain in Patients undergoing Elective Discectomy Surgery

Design
This study is a Randomized, double Blind controlled Clinical Trial with the Aim of Determining the Effect of preoperative Melatonin on the Severity of Postoperative pain in Patients undergoing Elective Discectomy Surgery. After Obtaining informed Consent, 80 Patients undergoing Surgical Disks, one or two Lumbar spaces and Anesthesia Classes 1 and 2 are divided into four Groups using Random Allocation Method.

Settings and conduct
The site of the study was in Imam Khomeini Hospital in Sari and was controlled by blind randomized random allocation method and divided into four Groups. Clinical Blind Attendants and Caregivers and Researchers and Analysts were blinded.

Participants/Inclusion and exclusion criteria
Entry Criteria: Confirmation of Diagnosis by Physical Exam, CT Scan and MRI; Patient's Willingness to participate in the Study and Obtaining informed consent; The candidate for Non-Emergency Discectomy Surgery; Age of 35-70 years Exit Criteria: The patient's unwillingness at any time to continue to participate in the Study; Emergency Discomtious Surgery; Involvement of more than two Lumbar Discs; use of opiate medication up to 24 hours before intervention; Alcohol orDrug abuse; incidence of each Type of an uncommon side Effect during Surgery

Intervention groups
Intervention group A: One Tablet of 3 mg Melatonin
Intervention group B: One Tablet of 5 mg Melatonin
Intervention group C: One Tablet of 10 mg Melatonin
Intervention group D: One Tablet of plasebo tablets is given to Patients one hour before Surgery.

Main outcome variables
Painless; Reduction of Nausea and Vomiting; Itching; Satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201701304365N20**
Registration date: **2017-02-16, 1395/11/28**
Registration timing: **prospective**

Last update: **2018-01-20, 1396/10/30**
Update count: **1**

Registration date
2017-02-16, 1395/11/28

Registrant information

Name
Afshin Gholipour Baradari

Name of organization / entity
Mazandaran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date
2017-04-16, 1396/01/27

Expected recruitment end date
2017-10-25, 1396/08/03

Actual recruitment start date
2017-04-16, 1396/01/27

Actual recruitment end date
2017-10-25, 1396/08/03
Trial completion date
empty

Scientific title
Effect of preoperative melatonin on pain intensity after lumbar disc surgery

Public title
Effect of melatonin on pain intensity after lumbar disc surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of the diagnosis using physical examination, computed tomography (CT) scan and magnetic resonance imaging (MRI) patient agreement and informed written consent candidate of elective discectomy surgery age 35 to 70 years
Exclusion criteria:
consumption of opium 24 hour before surgery drug or alcohol abuse any unusual complication during surgery Patients' unwillingness at any time to continue participation in this study emergency discectomy surgery involvement of more than two lumbar discs
Age
From **35 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Actual sample size reached: **79**
Randomization (investigator's opinion)
Randomized
Randomization description
table of random numbers
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants, care providers, Investigator and Outcome assessor are blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Mazandaran University of Medical Sciences
Street address
Moallem Square, Mazandaran University of Medical Sciences
City
Sari
Province
Mazandaran
Postal code
48189-33876
Approval date
2016-04-10, 1395/01/22
Ethics committee reference number
ir mazums rec 95 1821

Health conditions studied

1

Description of health condition studied
lumbar discopathy
ICD-10 code
G55.1
ICD-10 code description
Nerve root and plexus compressions in intervertebral disc disorders

Primary outcomes

1

Description
Pain after disc surgery
Timepoint
1, 6, 12, 24 hour after surgery
Method of measurement
VAS

Secondary outcomes

1

Description
Pruritus,Nausea and vomiting,Satisfaction of pain cotrol
Timepoint
1,6,12,24 hour after surgery
Method of measurement
VAS

Intervention groups

1

Description

Intervention A: Tablet Melatonin 3 mg, 1 hour before surgery

Category

Treatment - Drugs

2

Description

Intervention B: Tablet Melatonin 5 mg, 1 hour before surgery

Category

Treatment - Drugs

3

Description

Intervention C: Tablet Melatonin 10 mg, 1 hour before surgery

Category

Treatment - Drugs

4

Description

Control: Tablet Placebo, 1 hour before surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini General Hospital

Full name of responsible person

Afshin Gholipour Baradari, MD, CCMF, Associate Professor

Street address

Imam Khomeini Hospital, Amir Mazandaran Street, Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

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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

Sari 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

Mohammad Reza Habibi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The Researcher does not currently see the Need for Data sharing in this Study.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available