

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 or Drug 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

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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 control

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

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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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Latest degree

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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