Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison of Effects of melatonin and gabapentin on pain and anxiety following lumbar spine surgery

Protocol summary

Summary

In this study, the efficacy of melatonin and gabapentin in evaluating the anxiety and postoperative pain in lumbar spine surgery in patients referred to Golestan Hospital General Operative Room. A total of 90 patients were selected randomly in 3 groups of melatonin, gabapentin and placebo. 120 min before induction, melatononin, gabapentine and palacebo groups received 60 mg melatonin, 600 mg gabapentine and 5 ml distilled water, respectively. After transferring patients to surgical room, all will be taken care of under standard monitoring including electrocardiogram, pulse oximetry, non-aggressive blood pressure and heart rate. Meanwhile anxiety level in patients before surgery would be measured with a VAS. After prescription of 10 ml/kg isotonic liquids and preoxygenation for 3 min, all patients with a same procedure, 3 mg/kg midazolam, 2 mg/kg phentanyl, 4 mg/kg STP and 5 mg/kg atracurarium will be anesthesized. After intubation and fixation of tube, the vital symptoms including BP, HR and SpO2 will be measured. Anesthesizing process with 75% oxygen and isoflurane 8%is managed. At the end of the surgery and extubing the patient, the following parameters will be studied. -Need for remedy 1, 2, 6, 12 and 24 h after surgery -Pain intensity using VAS 1, 2, 6, 12 and 24 h after surgery -Satisfaction level of patients of analgesia with a quality score (perfect, good, average and poor) 1, 2, 6, 12 and 24 h after surgery All data will be recorded by a non-informed third person of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100436566N1**
Registration date: **2017-11-19, 1396/08/28**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name
Iren Amirpour
Name of organization / entity
Ahvaz Jundishapor University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapor University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effects of melatonin and gabapentin on pain and anxiety following lumbar spine surgery

Public title

Comparison of Effects of melatonin and gabapentin on pain and anxiety following lumbar spine surgery

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion area: Aged 18 and under 60 years old; ASA class ˋI and ˋIˋI; Spine surgery; Written permission of study entrance Exclusion area: Emergency surgery; tumor surgery; melatonin or gabapentin allergy; BMI higher than 35; pregnancy or breastfeeding; opioid 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: **30**
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
Ahvaz Jundishapur University of Medical Sciences
Street address
Khuzestan, Ahvaz
City
Ahvaz
Postal code
Approval date
2017-04-29, 1396/02/09
Ethics committee reference number
IR.AJUMS.REC.1396.86

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
R52.9
ICD-10 code description
Pain, unspecified

2

Description of health condition studied
Anxiety
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
Pain
Timepoint
2 h before until 24 h after opetration
Method of measurement
Visual Analogue Scale, questionnaire

2

Description
Anxiety
Timepoint
2 h before until 24 h after opetration
Method of measurement
Visual Analogue Scale, questionnaire

Secondary outcomes

1

Description
blood pressure
Timepoint
2 h before until 24 h after operation
Method of measurement
sphygmomanometer

2

Description
heart rate
Timepoint
2 h before until 24 h after operation
Method of measurement
Stetoscope

Intervention groups

1

Description
Oral gabapentin is given at a dose of 600 mg two hours before surgery
Category
Prevention

2

Description

Oral melatonin is given at 6 mg 2 hours before surgery

Category

Prevention

3

Description

Distilled water is used at a rate of 5 ml 2 hours before surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestasn Hospital

Full name of responsible person

Iren Amirpour

Street address

City

Ahvasz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapor University of Medical Sciences

Full name of responsible person

Reza Akhondzadeh

Street address

Faculty of Medicine, Jundishapour University of Medical Sciences

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz Jundishapor 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

Ahvaz Jundishapor University of Medical Sciences

Full name of responsible person

Fatemeh Javaherforoshzadeh

Position

Cardiac Anesthesia Fellowship

Other areas of specialty/work

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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