

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Oral melatonin Effect on pain after percutaneous lumbar disc decompression

Protocol summary

Study aim

Melatonin effect on pain and patient disability after percutaneous lumbar disc decompression

Design

If there was any response to medical treatment after 3 months they undergo percutaneous lumbar disc decompression. Then the patients were randomly placed in two groups of control (C) and melatonin (M) by Random Allocation Software 2.0 using block randomization method in groups of 10. There are 35 patients in each group. The patients group did not register in the file. So, the Physician performing the procedure and whom following the patients did not know about the patients grouping.

Settings and conduct

Study was done in patients with lumbar disc herniation who refer to the Rasoul Akram Hospital pain clinic. Patients who didn't respond to drug after 3 months the undergo PLDD and then randomly were divided in two groups by random allocation software and take their own drug in order to the group belongs to.

Participants/Inclusion and exclusion criteria

Patients with lumbar radicular moderate to high pain, lumbar disc herniation in 1 to 3 lumbar levels based on MRI and physical examination, that no respond to 3 months conservative treatment inserted to the study.

Intervention groups

After percutaneous laser disk decompression Patients randomly were divided into 2 groups. Both of the groups receive pregabalin, diclofenac and vitamin B1 daily for 3 months orally but control group received melatonin 3 mg for 3 months in addition.

Main outcome variables

1. ODI Index score (Oswestry disability index) 2. MacGill score 3. SLR degree, sptt, springing, bonet

General information

Reason for update

Acronym

PLDD

IRCT registration information

IRCT registration number: **IRCT20220514054846N1**

Registration date: **2024-02-26, 1402/12/07**

Registration timing: **retrospective**

Last update: **2024-02-26, 1402/12/07**

Update count: **0**

Registration date

2024-02-26, 1402/12/07

Registrant information

Name

seyedeh fatemeh morsali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 4279

Email address

fatemehmorssali@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-28, 1402/03/07

Expected recruitment end date

2023-09-20, 1402/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Oral melatonin Effect on pain after percutaneous lumbar disc decompression

Public title

Oral melatonin effect on pain after percutaneous lumbar disc decompression: a double-blind randomized clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Unilateral or bilateral chronic radicular low back pain. Moderate to high pain score (VAS 3 or higher). Confirmation of LDH in one to three lumbar levels based on MRI and physical examination findings. ASA class I-II. No respond to conservative treatments (at least for three months)

Exclusion criteria:

Include disc extrusion or sequestration. Disc height reduction of more than 50%. Severe spinal deformity. Tumor or spinal fracture or spondylolisthesis. Local or systemic infection. Use of anticoagulants. History of allergic reaction to study drugs. Pregnancy and breastfeeding. Severe disorders. Sudden onset of neurological deficit such as urinary and fecal incontinence. History of lumbar spine surgery. Peripheral neuropathy. Patient refusal.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

It was done as Random Allocation Block by (Random Allocation Software 2.0) in groups of 10 people.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients grouping will not record in the file, so the physician who perform the procedure and whom examine in the clinic will not aware of the patients grouping also they are not involve in the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran university of ethics committee

Street address

Rasool acam pain research center,4th step,department no 2.shr arar street,.

City

tehran

Province

Tehran

Postal code

1445613131

Approval date

2023-05-28, 1402/03/07

Ethics committee reference number

IR.IUMS.REC.1402.176

Health conditions studied

1

Description of health condition studied

Oral Melatonin effect on pain and disability after percutaneous disc decompression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determining the effect of oral melatonin on patients pain relief after lumbar disc decompression by SLR physical examination degree in intervention and control groups that will done by pain fellowship in pain clinic in specific time.

Timepoint

0,2 week,2nd month.3rd month

Method of measurement

Physical examination and determination SLR degree by pain fellowship in specific time.

2

Description

Determining the effect of oral melatonin on patients pain relief by (Oswestry Disability Index) using questionnaire that complete by pain fellowship.

Timepoint

0,2 week,2nd month.3rd month

Method of measurement

Determination of McGill pain index using questionnaire that complete by pain fellowship.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients in trial group, will take 3 mg melatonin tablets in addition to drugs belong to control group. The drugs will register electronically and Medicines are prepared from the Rasool Aakram Hospital pharmacy. The patient does not pay the cost of the melatonin drug and the cost is paid to the pharmacy by researcher separately . In this way, the drug producing company is same in all patients.

Category

Treatment - Drugs

2

Description

Control group:After PLDD patients will receive Diclofenac,pregsbaline and vitamin B1by electronic prescription.Drugs will be taken from Rasool Aakram Hospital pharmacy and drugs brand and company are the same in all patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool acram hospital

Full name of responsible person

Seyyede Fatemeh Morsali

Street address

4th floor,department no 2,pain research center of Rasool acram hospital,Shahr ara street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyede Fatemeh Morsali

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Iran University if medical science, Next to Milad Tower, Hemet Highway, Tehran

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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

Iran University of Medical Sciences

Proportion provided by this source

20

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

Iran University of Medical Sciences

Full name of responsible person

Seyyede Fatemeh Morsal

Position

fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Rasool Acram Pain Research Center Niayesh street,Sattarkhan ave,tehan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Morsali

Position

pain fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participants data can be shared

When the data will become available and for how long

starting one year after complete of study

To whom data/document is available

Data will be shared for academic institutions.

Under which criteria data/document could be used

The reason of needing data must be determine with detail.

From where data/document is obtainable

fatemehmorssali@yahoo.com

What processes are involved for a request to access data/document

Up to one month after request they can receive data.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

seyyede fatemehmorsali

Position

pain fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Rasool acram Pain Research Center, 4th step, building no 2, Rasool acram hospital, shahr ara street, sattarkhan

City

Tehran