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 devided in two groups by random allocation software and take their own drug inorde 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 melatonin3 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)

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+98 21 2258 4279

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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 qrouping will not record in the file, so the physition who perform the procedure and whom examine in the clinic will not aware of the patients qrouping 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 separatly . 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
Seyyedeh 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
Seyedeh Fatemeh Morsali

Street address
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
Seyedeh 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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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 needding 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