Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Role of clonidine in management of pain after lumbar discectomy

Protocol summary

Study aim
Determine the effect of Clonidine on pain relief after lumbar disc surgery
Design
Clinical trial with control group, with parallel groups, Triple blind, 60 patients
Settings and conduct
Two engines will be used in place of placebo and in a clinical trial in two parallel groups. During the entire study period, patients, staff and surgeons will be unaware of the two main study arms.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 70 years Weight 60 to 80 kg Having satisfaction Adherence of clinical signs and symptoms to MRI findings The presence of a disc in a lumbar space in an MRI Exit criteria: History of lumbar surgery Drug Addiction or Alcohol Pregnancy and lactation Previous use of the same drugs Seizures and other neurological diseases Intervention over a diskette only involves the use of a discectomy or diskette over a disk space Use of other medications the day before or after surgery (unwanted) The patient's disability is due to retardation, aphasia, visual impairment, and other things that prevent the patient from communicating. The patient's over-standard need for opioid and analgesic neuropathic drugs History of obstructive peripheral vascular disease
Intervention groups
Intervention group: Clonidine capsule form will given to patients. Control group: Placebo capsule form will given to patients.
Main outcome variables
Post-operative pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120527009878N11**
Registration date: **2019-10-20, 1398/07/28**
Registration timing: **prospective**

Last update: **2019-10-20, 1398/07/28**
Update count: **0**
Registration date
2019-10-20, 1398/07/28

Registrant information
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Recruitment status
Not yet recruiting
Funding source

Expected recruitment start date
2640-01-26, 2018/11/06
Expected recruitment end date
2640-06-27, 2019/04/06
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Role of clonidine in management of pain after lumbar discectomy

Public title
The effect of medication on reducing lumbar pain
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Age of 18 to 70 years Weight 60 to 80 kg Having satisfaction Adherence of clinical signs and symptoms to MRI findings The presence of a disc in a lumbar space in an MRI

Exclusion criteria:
History of lumbar surgery Drug or Alcohol Addiction Pregnancy and lactation Previous use of the same drugs Seizures and other neurological diseases Intervention over a diskette only involves the use of a discectomy or diskette over a disk space Use of other medications the day before or after surgery (unwanted) The patient's disability is due to retardation, aphasia, visual impairment, and other things that prevent the patient from communicating. The patient's over-standard need for opioid and analgesic neuropathic drugs History of obstructive peripheral vascular disease

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into case and control groups. Randomization will be done using the Gaussian command at www.random.org.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Two engines will be used in place of placebo and in a clinical trial in two parallel groups. During the entire study period, patients, staff and surgeons will be unaware of the two main study arms. The use of Visual Analogue Scale (VAS) will be done to measure pain in the lower limbs and wrists of patients receiving Clonidine and placebo. Clonidine used in the form of capsules and 2 hours before surgical intervention will be given to patients in the study group. Oral Gabapentin begins with a standard dose for the patient. The placebo capsule, taken in the shape and size and color and weight of the actual drug by the head nurse, is considered to be blind to 2 hours before surgery. Two arms of control and case will be mediation by an anesthetic protocol and a profile.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz university of medical sciences

Street address
Floor 3, Center building N 2, Tabriz university of medical sciences, Golgasht street.

City
Tabriz

Province
East Azarbaijan

Postal code
04133357310

Approval date
2018-08-27, 1397/06/05

Ethics committee reference number
IR.TBZMED.REC.1397.481

Health conditions studied

1

Description of health condition studied
Post-procedural Pain

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Post-operative pain

Timepoint
Clonidine used in capsule form and 2 hours before surgical intervention in the case group will be given to patients. After surgery for the first 24 hours and at the end of 6 hours, one physician who is blind to the study will record the parametric / VAS pain rate in the sheet. The amount of Opioid ingestion in the first 24 hours after surgery will also be measured for each patient.

Method of measurement
Using VAS (virtual analogue scale) to measure pain in the lower extremities and wrists of patients receiving clonidine and placebo.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Clonidine produced by Zahravi Tabriz Company will be given orally to the patients in the form of 0.2 mg tablet twice daily.
Category
Treatment - Drugs

2

Description
Control group: Placebo produced by Zahravi Tabriz Company will be given orally to the patients in the form of 0.2 mg tablet twice daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam reza hospital and Shohada hospital
Full name of responsible person
Javad Aghazadeh
Street address
Golgash street, Tabriz university of medical science.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Abolghasem Joyban
Street address
Headquarters No. 2, Third Floor of Research & Technology Dept. Golgasht Street , Tabriz University of Medical Sciences
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Javad Aghazade
Position
Neurosurgical Specialist - Neurosurgery
Latest degree
Specialist
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data is available for sharing.
When the data will become available and for how long
Start the access period 3 months after printing the results
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
Research and Therapeutic Use
From where data/document is obtainable
Resident of neurosurgery at Imam Reza Hospital 09143141602
What processes are involved for a request to access data/document
Three months after publication of results, the writing request were submitted in the Office of the Department of neurosurgery at Imam Reza Hospital in Tabriz and will be contacted with the relevant resident.
Comments