# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Jun 2026

## Assessment of cycloserine effect on neuropathic pain after lumbar disc herniation surgery

### Protocol summary

**Study aim**
Assessment of cycloserine effect on neuropathic pain after lumbar disc herniation surgery

**Design**
Clinical trial with control group, with parallel groups, double-blind, randomized by table of random numbers, phase 2-3 on 68 patients.

**Settings and conduct**
1. Patients are selected from lumbar disc evacuation candidates in one or two spaces during 6. 2. Randomization is done. 3. Entry and exit criteria are applied. 4. Each patient receives a capsule of medicine or placebo two hours before the operation. 5.Record the amount of pain and morphine consumption at regular intervals until the end of 24 hours May be. 6. The collected data are categorized within 24 hours. In this study, participants, the main researcher, health care personnel (physicians, nurses) who are responsible for patient care are blind to the study. 7. This study is performed in Shahid Madani Educational and Medical Center in Karaj.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 1. Age: 24 to 19 Between BMI .2 70 to 18 3. Having informed consent 4. Adaptation of clinical signs and symptoms to imaging findings Exclusion criteria: 1. Previous surgical intervention 2. History of alcohol or drug addiction 3. morphine complications during the study 4. Pregnancy 5 .Breastfeeding 6 .Psychiatric illnesses such as depression 7 .Nervous illnesses such as seizures 8 .Use of antidepressants Pain during the last 24 hours 9. Existence of internal diseases such as DM 10. Aphasia or visual impairment

**Intervention groups**
Control group: The whole group of patients in the control group is given a dose of capsule filled of Rice powder and the volume and weight of the drug are the same as in the intervention group. Intervention group: Cycloserine 250 g capsules are given to all members of the intervention group 2 hours before the start of surgery orally and in a single dose

**Main outcome variables**
1.lumbar pain 2.Morphine intake

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200115046150N1**
Registration date: **2020-09-12, 1399/06/22**
Registration timing: **retrospective**

Last update: **2020-09-12, 1399/06/22**
Update count: **0**

**Registration date**
2020-09-12, 1399/06/22

**Registrant information**

**Name**
Pouria Basiry

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 4436 8227

**Email address**
pouriabasiry@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-03-20, 1399/01/01

**Expected recruitment end date**
2020-06-21, 1399/04/01

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Assessment of cycloserine effect on neuropathic pain after lumbar disc herniation surgery

**Public title**

cycloserine effect on neuropathic pain decreasing

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age 18-70 years old BMI 19-24 Having informed consent Adaptation of clinical signs and symptoms to imaging findings

**Exclusion criteria:**

Candidate patients for laminectomy discectomy

**Age**

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

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, a simple random method based on a single sequence of Random allocations have been used. A table of random numbers has been used for this purpose.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, participants included the main researcher, health care personnel (physicians, nurses) who are responsible for patient care, and data collection officials regarding the type of drugs given to patients and also in which group each person Are blind.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

**Street address**

Office of the Ethics Committee, Second Floor, Deputy of Research and Technology, Saffarian Alley, 45 Golshahr Street, Karaj

**City**

Karaj

**Province**

Alborz

**Postal code**

3198764653

**Approval date**

2020-08-24, 1399/06/03

**Ethics committee reference number**

IR.ABZUMS.REC.1399.128

## Health conditions studied

**1**

**Description of health condition studied**

Lumbar disc herniation

**ICD-10 code**

G55.1

**ICD-10 code description**

Nerve root and plexus compressions in intervertebral disc disorders

## Primary outcomes

**1**

**Description**

lumbar pain

**Timepoint**

6,12,18,24 hours post operation

**Method of measurement**

visual analogue scale

## Secondary outcomes

**1**

**Description**

Morphine intake

**Timepoint**

6,12,18,24 hours post operation

**Method of measurement**

The volume of drug injected into the cc

## Intervention groups

**1**

**Description**

Intervention group: Cycloserine 250 g capsules are given to all members of the intervention group 2 hours before

the start of surgery orally and in a single dose.

**Category**

Treatment - Drugs

**2**

**Description**

Control group:The whole group of patients in the control group is given a dose of capsule filled of Rice powder and the volume and weight of the drug are the same as in the intervention group 2 hours before the start of surgery.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Madani Educational and Medical Center

**Full name of responsible person**

POuria Basiry

**Street address**

Shahid Madani Hospital, JahanshaMahan Boulevard, Taleghani Crossroads, Karaj

**City**

Karaj

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12345678

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**Email**

Madani@abzums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Alborz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Nouri Sepehr

**Street address**

Office of the Ethics Committee, Second Floor, Deputy of Research and Technology, Saffarian Alley, 45 Golshahr Street, Karaj

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**Phone**

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**Email**

Research@abzums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research, Alborz 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**

Alborz University of Medical Sciences

**Full name of responsible person**

Pouria Basiry

**Position**

Intern of medical doctor

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**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