Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Effect of N-acetyl cysteine versus placebo on clinical outcomes in patients with acute radicular lumbar pain: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of N-acetyl cysteine versus placebo on clinical outcomes in patients with acute radicular lumbar pain

Design

This is a double-blind randomized clinical trial, phase II, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with acute radicular lumbar pain referring to the Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Acute lumbar radicular pain due to disc herniation, A minimum pain intensity score of 4 or more based on the VAS, A minimum functional disability score of 30 or more based on disability index questionnaire, Symptoms start between the last 2 to 12 weeks, Exclusion criteria: Taking herbal medications or products or other supplements in the last 3 months, Spinal canal stenosis or intervertebral disc degeneration, Patients with progressive and severe motor symptoms, History of neuropathy for other reasons, History of lumbar surgery, Existence of any malignancy, Chronic liver or kidney disease, Hypersensitivity to N-acetyl cysteine

Intervention groups

Intervention group: Routine treatment plus N-acetyl cysteine tablet (manufactured by Osveh Pharmaceutical Co.) 600 mg every 12 hours for 2 months Control group: Routine treatment plus placebo tablet (manufactured by School of Pharmacy, Shahid Beheshti University) every 12 hours for 2 months

Main outcome variables

Primary outcome: Functional disability, the severity of pain, response to treatment Secondary outcome: Gastrointestinal or systemic adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N381**
Registration date: **2021-02-06, 1399/11/18**
Registration timing: **prospective**

Last update: **2021-02-06, 1399/11/18**
Update count: **0**

Registration date

2021-02-06, 1399/11/18

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of N-acetyl cysteine versus placebo on clinical outcomes in patients with acute radicular lumbar pain: a double-blind randomized clinical trial

Public title
Effect of N-acetyl cysteine versus placebo on clinical outcomes in patients with acute radicular lumbar pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 65 years, Acute lumbar radicular pain due to disc herniation, A minimum pain intensity score of 4 or more based on the VAS, A minimum functional disability score of 30 or more based on disability index questionnaire, Symptoms start between the last 2 to 12 weeks, Lack of proper response to NSAIDs and corticosteroids
Exclusion criteria:
Taking herbal medications or products or other supplements in the last 3 months, Spinal canal stenosis or intervertebral disc degeneration, Patients with progressive and severe motor symptoms, History of neuropathy for other reasons, History of lumbar surgery, Existence of any malignancy, Pregnancy or breastfeeding, Chronic liver or kidney disease, Hypersensitivity to N-acetyl cysteine
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as triple-blind
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2020-11-08, 1399/08/18
Ethics committee reference number
IR.UMSHA.REC.1399. 677

Health conditions studied

1

Description of health condition studied
Acute radicular lumbar pain
ICD-10 code
M46.06
ICD-10 code description
Spinal enthesopathy, lumbar region

Primary outcomes

1

Description
Functional disability
Timepoint
Before the intervention and in second, fourth, and eighth weeks after the intervention
Method of measurement
Using Oswestry Disability Index (ODI)

2

Description
The severity of pain
Timepoint
Before the intervention and in second, fourth, and eighth weeks after the intervention
Method of measurement
Using Visual Analog Scale (VAS)

3

Description
Response to treatment
Timepoint
8 weeks after the intervention
Method of measurement
Using Global Response Assessment (GRA)

Secondary outcomes

1

Description
Gastrointestinal or systemic adverse effects
Timepoint
In the second, fourth, and eighth weeks after the intervention
Method of measurement
By taking history

Intervention groups

1

Description
Intervention group: Routine treatment plus N-acetyl cysteine tablet (manufactured by Osveh Pharmaceutical Co.) 600 mg every 12 hours for 2 months
Category
Treatment - Drugs

2

Description
Control group: Routine treatment plus placebo tablet (manufactured by School of Pharmacy, Shahid Beheshti University) every 12 hours for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital in Hamadan city
Full name of responsible person
Zaeinab Sadat Seyedian
Street address
Sina Hospital, Mirzadeh Eshghi Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Zaeinab Sadat Seyedian
Position
Student of Pharmacy
Latest degree

Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Medical Pharmacy

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Person responsible for updating data

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Professor of Epidemiology

Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available