

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

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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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Contact

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Professor of Epidemiology

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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