Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of silymarin topical gel compared to placebo topical gel as adjunctive therapy on pain control after stroke: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of silymarin topical gel compared to placebo topical gel as adjunctive therapy on pain control after stroke

Design

This is a Phase III double-blind randomized clinical trial with a control group with parallel groups, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Besat Hospital in Hamadan city, involving 25 eligible patients with stroke. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 75 years; Stroke; Shoulder and scapula muscle pain and stiffness; Exclusion criteria: Pregnancy or breastfeeding; Kidney or liver failure; Use of painkillers; Substance abuse

Intervention groups

Intervention group: Standard treatment included pregabalin tablets 50 to 75 mg twice daily and duloxetine tablets 20 mg twice daily for 3 months plus 3% silymarin topical gel on the shoulder and scapula area twice daily for 3 months Control group: Standard treatment included pregabalin tablets 50 to 75 mg twice daily and duloxetine tablets 20 mg twice daily for 3 months plus placebo topical gel on the shoulder and scapula area twice daily for 3 months

Main outcome variables

Primary outcome: Mean pain score; Mean quality of life score; Degree and frequency of muscle cramps Secondary outcome: Local complications (redness, burning, itching)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N559**
Registration date: **2025-05-21, 1404/02/31**
Registration timing: **prospective**

Last update: **2025-05-21, 1404/02/31**
Update count: **0**

Registration date

2025-05-21, 1404/02/31

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of silymarin topical gel compared to placebo topical gel as adjunctive therapy on pain control after stroke: a double-blind randomized clinical trial

Public title
Effect of silymarin topical gel compared to placebo topical gel as adjunctive therapy on pain control after stroke

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 75 years Stroke Shoulder and scapula muscle pain and stiffness

Exclusion criteria:
Pregnancy or breastfeeding Kidney or liver failure Use of painkillers Substance abuse

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a double-blind study.

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, Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2025-04-13, 1404/01/24

Ethics committee reference number
IR.UMSHA.REC.1404.031

Health conditions studied

1

Description of health condition studied
Stroke

ICD-10 code
G46.4

ICD-10 code description
Cerebellar stroke syndrome

Primary outcomes

1

Description
Mean pain score

Timepoint
Before intervention and 3 months later

Method of measurement
Using Visual Analog Scale (VAS)

2

Description
Degree and frequency of muscle cramps

Timepoint
Before intervention and 3 months later

Method of measurement
Using clinical examination

Secondary outcomes

1

Description
Local complications (redness, burning, itching)
Timepoint
3 months after intervention
Method of measurement
By taking history

2

Description
Mean quality of life score
Timepoint
Before intervention and 3 months later
Method of measurement
Using World Health Organization Quality of Life Scale

Intervention groups

1

Description
Intervention group: Standard treatment included pregabalin tablets 50 to 75 mg twice daily and duloxetine tablets 20 mg twice daily for 3 months plus 3% silymarin topical gel on the shoulder and scapula area twice daily for 3 months
Category
Treatment - Drugs

2

Description
Control group: Standard treatment included pregabalin tablets 50 to 75 mg twice daily and duloxetine tablets 20 mg twice daily for 3 months plus placebo topical gel on the shoulder and scapula area twice daily for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital in Hamadan city
Full name of responsible person
Seyedeh Zahra Mousavi Golbar
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Sponsors / Funding sources

1

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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
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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