Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of Hypericum perforatum (Perforan) Tablets on Neurological Pain, Functional Independence and Severity of Depression in Patients with Spinal Cord Injuries

Protocol summary

Study aim
Determining the effect of Hypericum perforatum tablets (Perforan drug produced by Gol Daru Company) on neurological pain, functional independence, and depression severity in patients with spinal cord injury in the subacute phase

Design
A controlled, parallel-group, randomized, phase 0 clinical trial on 30 patients. The randomizer.org website was used for randomization.

Settings and conduct
The study site is Rofaideh Rehabilitation Hospital, Tehran, Iran. Patients hospitalized in the spinal cord injury ward with stable condition are used for rehabilitation and subacute phase treatments. Completing the consent form, random assignment to two control and treatment groups (simple randomization), and prescribing Perforan tablets for a 21-day period are the steps of the study. The severity of spinal cord injury is assessed using the ASIA scale and a demographic questionnaire is completed at the beginning of the study. Neurological pain severity, patient functional independence score, and Beck depression test are assessed at the beginning and end of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Sub-acute phase Exclusion criteria: Intolerance or adverse laboratory changes, drug interactions

Intervention groups
Intervention group: Perforan tablets from Gol Daru Company, licensed by the Food and Drug Administration of Iran, 3 times a day, one tablet each time. Control group: Without receiving a placebo

Main outcome variables
Neurological pain; Functional independence score; Depression severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241118063767N1**
Registration date: **2024-12-04, 1403/09/14**
Registration timing: **prospective**

Last update: **2026-01-06, 1404/10/16**
Update count: **1**

Registration date
2024-12-04, 1403/09/14

Registrant information

Name
Mansooreh Sadat Mojani Qomi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2641 5547

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mansooreh.moujani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-19, 1403/10/30

Expected recruitment end date
2025-06-21, 1404/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effect of Hypericum perforatum (Perforan) Tablets on Neurological Pain, Functional Independence and Severity of Depression in Patients with Spinal Cord Injuries

Public title
Study the Effect Hypericum perforatum medicine on spinal cord injury

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Full consent to participate in the study At least one month has passed from the lesion and the patient is in the sub-acute phase

Exclusion criteria:
Acute and chronic phases of spinal cord injury Intolerance, allergic reaction or unexpected laboratory changes identified by the patient or specialist physician Medications that may interact with Perforan tablets (Such as cytochrome P450 inducers, SSRI and MAOI drugs, blood pressure lowering drugs, anticoagulant drugs)

Age
No age limit

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization: The allocation of individuals to groups is done in the form of a four-block random allocation. First, the size of each block is specified (four-block), then the list of blocks is specified with the help of the randomizer.org website and numbers are assigned to them (numbers 1 to 15 for 60 people), and each of the numbers on the list is placed in an envelope for its own treatment allocation. Then, individuals entering the study randomly select envelopes containing numbers between one and 15, and the allocation of individuals to two groups, 1 and 2, is determined based on a list of blocks of four for each number

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Islamic Azad Tehran Medical Science University Pharmacy and Pharmaceut

Street address
Tehran Medical Sciences of Islamic Azad Uninversity, Gole-Yakh Ave., Ayeneh Blv., Amir Pabarja Ave., Dr. Shariati Ave.

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Tehran

Postal code
1916893813

Approval date
2024-11-12, 1403/08/22

Ethics committee reference number
IR.IAU.PS.REC.1403.474

Health conditions studied

1

Description of health condition studied
Spinal Cord Injury

ICD-10 code
T09.3

ICD-10 code description
Injury of spinal cord, level unspecified

Primary outcomes

1

Description
Neurological Pain

Timepoint
Before the start of the intervention and 21 days after the start of treatment

Method of measurement
Numeric Rating Scale

2

Description
Functional Independence

Timepoint
Before the start of the intervention and 21 days after the start of treatment

Method of measurement
Functional Independence Measure (FIM) Questionnaire

3

Description
Depression severity

Timepoint
Before the start of the intervention and 21 days after the

start of treatment

Method of measurement

Beck Depression Inventory

4

Description

Spinal Cord Independence Measure

Timepoint

Before the start of the intervention and 21 days after the start of treatment

Method of measurement

Spinal Cord Independence Measure (SCIM) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Perforan tablets (Hypericum perforatum), Gol Daru Company. It has a license from the Food and Drug Administration, one tablet 3 times a day.

Category

Rehabilitation

2

Description

Control group: No placebo

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofaydeh Rehabilitation Center

Full name of responsible person

Seyed Majid Akhavan Hejazi

Street address

Rofaydeh Rehabilitation Center, Shahid Nemati St., Southern Salimi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Masoud parsania

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Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Ayeneh Blv.,Pabarja St., Shariati Ave.

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Mansooreh Sadat Mojani Qomi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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
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
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data about the main outcome or similar can be shared.
When the data will become available and for how long
After publication the results
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
To write a meta-analysis
From where data/document is obtainable
Mansooreh Sadat Mojani Qomi through sending email to mansooreh.moujani@gmail.com
What processes are involved for a request to access data/document
Up to about one month after application if results are published
Comments