Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effectiveness of Ultrasound-Guided Internal Heat Acupuncture for Alleviating Posterior Lumbar Nerve Pain and Modulating Serum IL1-β, TNF-α, and PGE2 Levels.

Protocol summary

Study aim

This study is critical not just for increasing our understanding of PLNP, but also for developing novel, evidence-based therapies that might greatly improve the quality of life for those living with this terrible disorder.

Design

A concealed, experimental, blinded, randomized clinical trial with a control group design of 30 patients enrolled between October 2023 and November 2023 and followed for 4 weeks

Settings and conduct

This will be conducted at The First People Hospital,Wuhan &trial assesor blind

Participants/Inclusion and exclusion criteria

Patients aged between 18-65 years diagnosed with PLNP and reporting a pain level of at least 4 on a 10-point visual analog scale (VAS) were eligible for the study. Exclusion criteria included pregnancy, current use of anti-inflammatory medications, history of spinal surgery, and contraindications to acupuncture.

Intervention groups

1. UGIHA Group: Patients in the UGIHA group received acupuncture sessions twice a week for four weeks. A 0.3 mm × 40 mm disposable needle (DongBang Acupuncture Inc., Korea) was percutaneously inserted and advanced to a depth of 15-25 mm into the intervertebral foramen under real-time ultrasound guidance. The needle was then electronically activated to produce heat. Acupuncture points targeted specific regions of discomfort or dysfunction.(13) 2. Control Group: Participants in the control group received non-therapeutic ultrasound therapy sessions twice a week for four weeks. The ultrasound therapy was administered without the application of heat and did not involve needle insertion

Main outcome variables

1. Primary Outcome: Pain severity was assessed using a 10-point visual analog scale (VAS) at baseline, after the 4-week intervention period, and during follow-up visits. 2. Secondary Outcomes: Serum levels of IL1β, TNF-α, and PGE2 were measured before and after the treatment period using established biochemical assays.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231026059863N1**
Registration date: **2023-10-31, 1402/08/09**
Registration timing: **retrospective**

Last update: **2023-10-31, 1402/08/09**
Update count: **0**

Registration date

2023-10-31, 1402/08/09

Registrant information

Name
Daojing Su

Name of organization / entity
Hubei University of Medicine

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China

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+86 150 0273 5690

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zhangandy@taihehospital.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-15, 1402/07/23

Expected recruitment end date

2023-10-18, 1402/07/26

Actual recruitment start date

2023-10-17, 1402/07/25

Actual recruitment end date

2023-10-23, 1402/08/01

Trial completion date

empty

Scientific title

Effectiveness of Ultrasound-Guided Internal Heat Acupuncture for Alleviating Posterior Lumbar Nerve Pain and Modulating Serum IL1-β, TNF-α, and PGE2 Levels.

Public title

effect of Ultrasound-Guided Internal Heat Acupuncture for Alleviating Posterior Lumbar Nerve Pain and Modulating Serum IL1-β, TNF-α, and PGE2 Levels.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged between 18-65 years diagnosed with PLNP and reporting a pain level of at least 4 on a 10-point visual analog scale (VAS) were eligible for the study.

Exclusion criteria:

Exclusion criteria included pregnancy, current use of anti-inflammatory medications, history of spinal surgery, and contraindications to acupuncture

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants who fulfilled the inclusion criteria were selected convenient sampling technique and were then allocated randomly to Group A and Group B using lottery method. This distribution process is hidden between participants and researchers. This was done by a research assistant who did not participate in any further research.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study was double-blinded. The outcome assessor who was blinded to the therapy group was recruited to take readings at pre-treatment and post-treatment values. And the patients were also blinded as they didn’t know they all have the same disorder and different techniques had been given to these patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of the First People's Hospital

Street address

Zhifang Culture Avenue, Jiangxia Distric Wuhan City

City

Wuhan

Postal code

442000

Approval date

2023-10-01, 1402/07/09

Ethics committee reference number

Ref/ET/FPH/01/01-10-2023

Health conditions studied

1

Description of health condition studied

Posterior Lumbar Nerve Pain

ICD-10 code

M54. 16

ICD-10 code description

Posterior Lumbar Nerve Pain

Primary outcomes

1

Description

1. Primary Outcome: Pain severity was assessed using a 10-point visual analog scale (VAS) at baseline, after the 4-week intervention period, and during follow-up visits.

Timepoint

4 weeks

Method of measurement

1. Primary Outcome: Pain severity was assessed using a 10-point visual analog scale (VAS)

Secondary outcomes

1

Description

Secondary Outcomes: Serum levels of IL1β, TNF-α, and PGE2 were measured before and after the treatment period using established biochemical assays.

Timepoint

4 weeks

Method of measurement

Secondary Outcomes: Serum levels of IL1β, TNF-α, and PGE2 were measured before and after the treatment period using established biochemical assays.

Intervention groups

1

Description
Intervention group: 1. Ultrasound-guided internal heat acupuncture Group: Patients in the UGIHA group received acupuncture sessions twice a week for four weeks. A 0.3 mm × 40 mm disposable needle (DongBang Acupuncture Inc., Korea) was percutaneously inserted and advanced to a depth of 15-25 mm into the intervertebral foramen under real-time ultrasound guidance. The needle was then electronically activated to produce heat. Acupuncture points targeted specific regions of discomfort or dysfunction

Category
Treatment - Other

2

Description
Control group: Participants in the control group received non-therapeutic ultrasound therapy sessions twice a week for four weeks. The ultrasound therapy was administered without the application of heat and did not involve needle insertion.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
The First People's Hospital

Full name of responsible person
Zengfeng Cheng

Street address
Zhifang Culture Avenue, Jiangxia Distric Wuhan City

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Sponsors / Funding sources

1

Sponsor

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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?
No

Title of funding source
No

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
Taihe Hospital affiliated to Hubei University of Medicine

Full name of responsible person
Daojing Su

Position
Professor

Latest degree
Master

Other areas of specialty/work
Rehabilitation management

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Person responsible for scientific inquiries

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Name of organization / entity
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Wuhan/Concorde Jiangnan Hospital

Full name of responsible person

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Position

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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Effectiveness of Ultrasound-Guided Internal Heat Acupuncture for Alleviating Posterior Lumbar Nerve Pain and Modulating Serum IL1-β, TNF-α, and PGE2 Levels.

When the data will become available and for how long

When the trial has been completed after the end November 2023.The data will be available for the future use and after the completion of the trial when it get published approximately after the 4 weeks in the end of the November 2023.The summary will be available after the article get published

To whom data/document is available

It will be available to all teaching institue and hospital for the better cure of the patient and more over it will be avilable for the researcher as wel

Under which criteria data/document could be used

Only for the research and for the benefits of the public

From where data/document is obtainable

Daojing Su Orthopedic Rehabilitation(1 Ward) of Shiyan Taihe Hospital affiliated to Hubei University of Medicine 32 renmin south road,maojian district,shiyan city,hubei province 605278189@qq.com

What processes are involved for a request to access data/document

By application sent to 605278189@qq.com

Comments