

Clinical efficacy of ultra-laser irradiation combined with gabapentin on elderly patients with cervical spondylotic radiculopathy

Submission date 10/03/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/03/2025	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/05/2026	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cervical spondylotic radiculopathy (CSR) is a common degenerative spinal disorder that causes neck pain, nerve root compression, and neurological symptoms in the upper limbs. This study aims to evaluate the clinical effectiveness and safety of ultra-laser irradiation combined with gabapentin compared to gabapentin alone in elderly patients with CSR, focusing on pain relief, quality of life improvement, and adverse reactions.

Who can participate?

Elderly patients (aged 60 years and over) diagnosed with cervical spondylotic radiculopathy

What does the study involve?

Participants are randomly allocated to be treated with either ultra-laser irradiation + gabapentin or gabapentin alone.

What are the possible benefits and risks of participating?

Benefits: Potential reduction in neck pain, improved nerve function, and better quality of life.

Risks: Possible mild side effects such as dizziness, fatigue, nausea, and ataxia, though fewer side effects are expected with laser therapy compared to drug treatment alone.

Where is this study taking place?

First People's Hospital of Fuyang District, Hangzhou (China)

When is the study starting and how long is it expected to run for?

June 2024 to September 2024

Who is funding the study?

First People's Hospital of Fuyang District, Hangzhou (China)

Who is the main contact?

Zhou Yu, yuz0531@163.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Study information

Scientific Title

A randomized controlled trial on the clinical efficacy of ultra-laser irradiation combined with gabapentin in the treatment of elderly patients with cervical spondylotic radiculopathy

Study objectives

Ultra-laser irradiation combined with gabapentin is more effective than gabapentin alone in reducing pain and improving health outcomes in elderly patients with cervical spondylotic radiculopathy.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 18/06/2024, Ethics Committee of the First People's Hospital of Fuyang District, Hangzhou (Room 403, Science and Education Administration Building, No. 429, North Ring Road, Fuchun Street, Fuyang District, Hangzhou, 311400, China; +86 (0)571-63157868; 25179144@qq.com), ref: 2024-LW(067)

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Efficacy, Safety, Treatment

Health condition(s) or problem(s) studied

Cervical spondylotic radiculopathy

Interventions

Patients are divided into the observation group and control group 1:1 with the help of a random number table.

Observation group:

Ultra-laser irradiation + gabapentin (oral capsules, starting dose 300 mg, titrated up to 2400 mg /day, treatment for three courses of 10 days each).

Control group:

Gabapentin alone (same dosage protocol as the observation group)

Intervention Type

Mixed

Primary outcome(s)

Pain relief measured by the Numerical Rating Scale (NRS/NPRS) at baseline and after three courses of treatment

Key secondary outcome(s)

1. Health-related quality of life improvement assessed by EuroQol-five dimensions (EQ-5D) questionnaire at baseline and after treatment
2. Incidence of adverse reactions (gastrointestinal discomfort, dizziness, lethargy, edema, rash, ataxia, fatigue) recorded throughout the study

Completion date

30/09/2024

Eligibility

Key inclusion criteria

1. Diagnosed with cervical spondylotic radiculopathy according to Rehabilitation Guidelines for Diagnosis and Treatment of Cervical Spondylosis (2010)
2. Aged ≥ 60 years
3. No history of peripheral nerve disease
4. No severe systemic diseases (cardiovascular, respiratory, digestive, liver, kidney disorders)
5. No opioid, NSAID, antidepressant, or antiepileptic drug use in the past month
6. Willingness to participate and signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

60 years

Upper age limit

120 years

Sex

All

Total final enrolment

160

Key exclusion criteria

1. Severe osteoporosis or bone tuberculosis
2. Nerve-related disorders not caused by cervical spondylotic radiculopathy (e.g., thoracic outlet syndrome, carpal tunnel syndrome, scapulohumeral periarthritis)
3. Severe cardiovascular, cerebrovascular, hepatic, renal, or hematopoietic diseases
4. Poor treatment adherence or incomplete clinical data
5. Congenital musculoskeletal disorders (e.g., congenital torticollis, congenital myopathy)

Date of first enrolment

18/06/2024

Date of final enrolment

01/09/2024

Locations**Countries of recruitment**

China

Study participating centre

The First People's Hospital of Fuyang District, Hangzhou
Room 403, Science and Education Administration Building
No. 429, North Ring Road
Fuchun Street
Fuyang District
Hangzhou
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311400

Sponsor information

Organisation

The First People's Hospital of Fuyang District, Hangzhou

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The First People's Hospital of Fuyang District, Hangzhou

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request Zhou Yu (yuz0531@163.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/11/2025	05/05/2026	Yes	No