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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

Registration date
13/03/2025

Overall study status
Completed

Last Edited
12/03/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/06/2024

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

Age group
Senior

Lower age limit
60 Years

Sex
Both

Target number of participants
160

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
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Sponsor information

Organisation
The First People's Hospital of Fuyang District, Hangzhou

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The First People's Hospital of Fuyang District, Hangzhou

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

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