

# Enhancing chronic migraine preventive therapy: laser acupuncture as an add-on treatment for patients with unsatisfactory pharmacological effect

<b>Submission date</b> 17/01/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/01/2024	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/02/2026	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Laser acupuncture is a proven non-invasive treatment with effects comparable to traditional acupuncture in chronic pain diseases, and it exhibits fewer adverse effects in treating headaches. However, recent studies lack sufficient evidence to support its application in chronic migraine (CM) in adults. This study aims to investigate the efficacy and safety of laser acupuncture (LA) as an add-on preventive therapy for CM.

### Who can participate?

Adult patients with CM aged over 18 years old who have unsatisfactory pharmacological effects

### What does the study involve?

In this study, participants will be randomly assigned to either LA or a sham control procedure, aiming to investigate the efficacy and safety of LA as an add-on preventive therapy for CM.

### What are the possible benefits and risks of participating?

Participants with poor-controlled CM may benefit by having their pharmacological treatment effect enhanced by add-on LA preventive therapy. There are risks of any of the following adverse events occurring during LA, such as nausea, dizziness, local paresthesia, local heat sensation, fatigue, somnolence, and ecchymosis.

### Where is the study run from?

Taichung Veterans General Hospital (Taiwan)

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

January 2022 to December 2023

Who is funding the study?

Department of Traditional Chinese Medicine, Taichung Veterans General Hospital. This research did not receive any specific grants from public, commercial, or not-for-profit funding agencies.

Who is the main contact?

1. Chi-Sheng Wang, sam7227632@gmail.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Chi Sheng Wang

### ORCID ID

<https://orcid.org/0000-0003-0842-9875>

### Contact details

Taichung Veterans General Hospital

No. 1650, Taiwan Boulevard, Sec. 4

Taichung City

Taiwan

40705

+886933375721

saintchi@vghtc.gov.tw

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Chi Sheng Wang

### Contact details

Taichung Veterans General Hospital

No. 1650, Taiwan Boulevard, Sec. 4

Taichung City

Taiwan

40705

+886933375721

sam7227632@gmail.com

## Additional identifiers

## Study information

### Scientific Title

Laser acupuncture for chronic migraine

Participants: Chronic migraine (CM) patients with unsatisfactory pharmacological effects

Intervention: Laser acupuncture (LA) as an add-on preventive therapy

Comparisons: Sham treatment as a control group

Outcomes: Changes in monthly migraine days (MMD) and acute headache medications usage days per month from baseline

### **Study objectives**

Laser acupuncture enhances the pharmacological treatment effect as an add-on preventive therapy for individuals with poor-controlled CM

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 04/05/2022, Institutional Review Board I &II of Taichung Veterans General Hospital (No. 1650, Taiwan Boulevard, Sec. 4, Taichung, 407219, Taiwan; +886-4-23592525 #4006; irbtc@vghtc.gov.tw), ref: CF22082B

### **Study design**

Single-blind randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Chronic migraine

### **Interventions**

This study is a single-blind randomized controlled trial, conducted from January 2022 to November 2023, aimed to investigate the efficacy and safety of laser acupuncture (LA) as an add-on preventive therapy for chronic migraine (CM) in patients with unsatisfactory pharmacological effects.

The intervention comprises non-invasive laser stimulation energy of 4.5 J for 30 seconds at each of the following acupoints: bilateral Cuanzhu (BL2), Fengchi (GB20), Taiyang (EX-HN5), Shuaigu (GB8), Hegu (LI4), Taichong (LR3) and midline Yintang (EX-HN3). Participants were randomized by computer software (Excel 2016 for Windows).

### **Study arms:**

Experimental: laser acupuncture

CM patients with unsatisfactory pharmacological effects receive laser acupuncture for 8 sessions that spanned 4 weeks.

Device intervention: Laser stimulation energy of 4.5 J for 30 seconds at each of the following acupoints: bilateral Cuanzhu (BL2), Fengchi (GB20), Taiyang (EX-HN5), Shuaigu (GB8), Hegu (LI4), Taichong (LR3) and midline Yintang (EX-HN3)

Sham Comparator: Sham treatment

Sham treatment had no laser output.

Device intervention: Sham treatment with no laser output, stimulate the same acupoints as the

laser acupuncture group as follows: 30 seconds at bilateral Cuanzhu (BL2), Fengchi (GB20), Taiyang (EX-HN5), Shuaigu (GB8), Hegu (LI4), Taichong (LR3) and midline Yintang (EX-HN3)

Follow-up activity.

After completing the study and unblinding, we will provide authentic laser acupuncture to individuals randomized to the Sham group.

Intervention provider

The laser application procedures will be performed by the same experienced physician who was a well-trained and licensed Chinese medicine practitioner in Taiwan. The execution process adhered to the regulations of the Taiwan Ministry of Health and Welfare.

Modes of delivery

The modes of delivery involve trained traditional Chinese medicine practitioners providing interventions face-to-face and individually.

The type(s) of location(s) where the intervention occurred

The entire treatment course, lasting approximately 10 minutes per session, was conducted in a dedicated treatment room affiliated with the Department of Traditional Chinese Medicine at Taichung Veterans General Hospital. The treatment protocol consisted of 8 sessions spanning 4 weeks.

## Intervention Type

Device

## Phase

Phase III

## Drug/device/biological/vaccine name(s)

Laser acupuncture device

## Primary outcome(s)

Changes in the number of monthly migraine days from baseline measured using a headache diary at each of the three follow-up time points (4th, 8th and 12th weeks) after randomization

## Key secondary outcome(s)

The following secondary outcome measures were measured at each of the three follow-up time points (4th, 8th and 12th weeks):

1. The proportion of patients with a  $\geq 30\%$  reduction in migraine days measured using a headache diary
2. Changes in the following parameters: (1) headache duration measured using a headache diary; (2) headache severity measured using a Numerical Rating Scale (NRS) and (3) headache-related disability measured using the Migraine Disability Assessment Score (MIDAS)
3. Acute headache medications usage days per month measured using a headache diary

## Completion date

01/12/2023

## Eligibility

### Key inclusion criteria

1. Aged >20 years old and had CM managed pharmacologically, including preventive and/or acute migraine medications, and in addition, those who had refused preventive agents despite the recommendation of the neurologist
2. Unsatisfactory effect of current pharmacological treatments, defined by self-reporting
3. A minimum of a one-year history of migraine with or without aura

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

20 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

60

**Key exclusion criteria**

1. Received another LA therapy or traditional acupuncture at baseline
2. Migraine onset after the age of 50
3. Cognitive or psychological impairment interfering with the participant's ability to receive LA protocol and describe symptoms
4. Patients with missing data at baseline or during the follow-up period

**Date of first enrolment**

01/04/2022

**Date of final enrolment**

01/09/2023

**Locations****Countries of recruitment**

Taiwan

**Study participating centre**

**Taichung Veterans General Hospital**

No. 1650, Taiwan Boulevard, Sec. 4

Taichung City

Taiwan  
40705

## Sponsor information

### Organisation

Taichung Veterans General Hospital

### ROR

<https://ror.org/00e87hq62>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Taichung Veterans General Hospital

### Alternative Name(s)

, TCVGH

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

China

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request.

The data collected from individual participants during the trial, once identified, will be accessible. This includes the Study Protocol, Statistical Analysis Plan, and Informed Consent Form. The data will be available immediately after publication and will have no set end date.

Researchers interested in accessing the data can make requests by submitting a methodologically sound proposal aligned with the approved proposal's aims. The principal investigator, Wang Chi-Sheng, will maintain the data indefinitely.

To submit proposals and gain access to the data, requestors should contact [sam7227632@gmail.com](mailto:sam7227632@gmail.com). However, access will only be granted after signing a data access agreement, ensuring responsible and ethical use of the information.

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		28/08/2024	02/09/2024	Yes	No
<a href="#">Abstract results</a>		23/06/2025	02/02/2026	No	No
<a href="#">Protocol file</a>			19/01/2024	No	No
<a href="#">Statistical Analysis Plan</a>			19/01/2024	No	No