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

Submission date
17/01/2024

Recruitment status
No longer recruiting

Registration date
19/01/2024

Overall study status
Completed

Last Edited
02/09/2024

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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

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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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

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

Pharmaceutical study type(s)
Not Applicable

Phase
Phase III

Drug/device/biological/vaccine name(s)
Laser acupuncture device

Primary outcome measure
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

Secondary outcome measures
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 ≥ 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

Overall study start date
01/01/2022

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

Age group
Mixed

Lower age limit
20 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
60

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
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40705

Sponsor information

Organisation
Taichung Veterans General Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.vghtc.gov.tw/

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

Publication and dissemination plan
We plan to analyze the current data and draft a manuscript focusing on results with statistical differences. Subsequently, we intend to submit the manuscript for publication in academic journals.

Intention to publish date
01/02/2024

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. 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?
Protocol file			19/01/2024	No	No
Statistical Analysis Plan			19/01/2024	No	No
Results article		28/08/2024	02/09/2024	Yes	No