Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the Effectiveness of High-Intensity Laser Therapy (HPLT) and Low-Level Laser Therapy (LLLT) in the Management of Idiopathic facial nerve palsy (Bell’s palsy)

Protocol summary

Study aim
The effectiveness of high-power laser therapy , low-power laser therapy on improving physical function, quality of life, facial palsy severity, and nerve conduction in patients with Bell's palsy

Design
A randomized, double-blind, controlled clinical trial on 30 patients with Bell's palsy.

Settings and conduct
Patients with acute Bell's palsy diagnosed by neurologists from 3 hospitals are referred to the Shohada Center after starting standard treatment and after obtaining informed consent are randomly assigned to three groups: HPLT treatment, LLLT treatment, and sham laser treatment. Before starting laser therapy (time zero), patients evaluated using the questionnaires, and a conduction study will be taken from the facial nerve. Subsequently, 10 sessions of laser therapy (every other day) will be performed. For follow-up, immediately after the end of treatment and one month later, patients will be evaluated again using the questionnaires and edx evaluation, and will be analyzed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18-70 years, acute unilateral Bell's palsy within the past 10 days, Beckman score ≥3 at base, standard drug therapy informed consent. Exclusion criteria: palsy other than Bell's, previous history of Bells , history of laser sensitivity or conditions that contraindications, malignancy, pregnancy or lactation, chronic neurological diseases, physiotherapy before study

Intervention groups
Patients in high-power and low-power laser groups will receive 10 sessions of laser therapy. In the placebo group, patients will lie on a bed for 10 sessions and be positioned in exactly the same location as the laser therapy groups but no laser radiation will be applied.

Main outcome variables
effectiveness of HPLT and LLLT on improving physical function, quality of life, facial paralysis severity, and nerve conduction in patients with Bell's palsy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260201068723N1**
Registration date: **2026-02-16, 1404/11/27**
Registration timing: **prospective**

Last update: **2026-02-16, 1404/11/27**
Update count: **0**

Registration date
2026-02-16, 1404/11/27

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01

Expected recruitment end date
2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of High-Intensity Laser Therapy (HPLT) and Low-Level Laser Therapy (LLLT) in the Management of Idiopathic facial nerve palsy (Bell’s palsy)

Public title

Comparison of the effects of low-power and high-power lasers in the treatment of Bell's palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Age between 18 and 70 years old 2. Diagnosis of acute unilateral Bell's palsy within the past 10 days. The diagnosis must be made clinically and by ruling out other causes. 3. House-Brackmann scale score ≥3 at baseline 4. Receive standard drug treatment (corticosteroids ± antiviral drugs) 5. Ability and willingness to provide written informed consent 6. Possibility to attend follow-up meetings until the end

Exclusion criteria:

1. Facial palsy with a cause other than Bell's palsy, such as: stroke, tumors (such as acoustic neuroma), Lyme disease, Ramsey-Hunt syndrome, trauma or surgical injury 2. Previous history of Bell's palsy or facial nerve palsy on the same side 3. History of laser sensitivity or conditions that contraindications to laser use, such as: Photosensitive epilepsy, Use of photosensitizing medications 4. Open wound or active infection or skin disease in the treatment area 5. Presence of malignancy in the face or neck area 6. Pregnancy or breastfeeding 7. major chronic neurological diseases such as MS 8. Participation in other concurrent intervention studies 9. Starting physiotherapy or electrical stimulation before entering the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, after identifying eligible patients and obtaining written informed consent, patients are randomly assigned to one of three intervention groups: high-power laser, low-power laser, and placebo laser. Block randomization is used to randomly assign individuals. Randomization is performed in blocks of six with an allocation ratio of 1:1:1.In each block of six, two patients are assigned to each of the three study groups, but the order of patient allocation within each block is determined completely randomly. The unit of randomization in this study is the individual, and each patient is placed in one of the study groups independently and without knowledge of the group allocation of other patients. Stratified randomization is not used in this study.The random sequence is generated by SPSS statistical software and by an individual independent of the research team. After generating the random sequence based on blocks of six, the group allocations are placed in sealed and numbered envelopes in a sequential manner. These envelopes are opened in the order of patients entering the study and by the operator implementing the intervention. The principal investigator, patients, and outcome assessors remain blind to the type of intervention assigned until the end of data collection. Allocation concealment is achieved through the use of sealed and numbered consecutive envelopes. The envelopes and random sequence are prepared by an independent individual.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are unaware of the type of intervention they receive (high-power laser, low-power laser, or placebo laser). The placebo laser is identical to the real laser in terms of device appearance, sound, probe contact with the skin, and treatment duration, and does not emit any effective therapeutic radiation. All participants are informed of their participation in a clinical trial and the possibility of being assigned to each group before entering the study, and written informed consent is obtained from them. The principal investigator of the study is not involved in the process of assigning patients to groups and implementing the intervention, and remains blind to the type of intervention assigned to each patient. The randomization sequence and allocation envelopes are prepared by an individual independent of the research team. The laser interventions are performed by an operator who has no role in data collection or outcome assessment. The operator is aware of the type of laser treatment but does not intervene in the analysis of the results and assessment of the outcomes. The individuals responsible for collecting the data and assessing the clinical outcomes are blinded to the group allocation and have no knowledge of the type of intervention the patients received. The statistical analysis of the data is performed by a researcher who is unaware of the type of intervention each group received, and the groups are identified only by code. Individuals who participate in the preparation of the draft of the article remain blinded to the group allocation until the end of the statistical analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Shahid Arabi St, Yaman St, Shahid Chamran Highway, Velenjak, Tehran
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Approval date
2026-01-19, 1404/10/29
Ethics committee reference number
IR.SBMU.MSP.REC.1404.678

Health conditions studied

1

Description of health condition studied
Bell's palsy
ICD-10 code
G51.0
ICD-10 code description
Bell's palsy

Primary outcomes

1

Description
Facial Disability Index (FDI) score
Timepoint
Before starting laser therapy (time zero), immediately after the end of treatment with 10 laser sessions, and one month after the end of treatment.
Method of measurement
A short, self-report questionnaire consisting of 10 items or questions.

2

Description
House-Brackmann system score
Timepoint
Before starting laser therapy (time zero), immediately after the end of treatment with 10 laser sessions, and one month after the end of treatment.
Method of measurement
Evaluation of facial nerve function by physician's examination

3

Description
Sunnybrook Facial Grading System score
Timepoint
Before starting laser therapy (time zero), immediately after the end of treatment with 10 laser sessions, and one month after the end of treatment.
Method of measurement
Evaluation of facial nerve function by physician's examination

4

Description
Electrodiagnostic test findings
Timepoint
Before starting laser therapy (time zero), immediately after the end of treatment with 10 laser sessions, and one month after the end of treatment.
Method of measurement
Findings from muscle and nerve conduction studies

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 10 patients with Bell's palsy will undergo 10 sessions of low-level laser treatment.
Category
Rehabilitation

2

Description
Intervention group2: 10 patients with Bell's palsy will undergo 10 sessions of high power laser treatment.
Category
Rehabilitation

3

Description
Intervention group3: 10 patients with Bell's palsy will receive 10 sessions of sham laser treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Shohada Tajrish hospital

Full name of responsible person
Fatemeh Hojjati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Afshin Zarghi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammadreza Saadati

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

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Person responsible for updating data

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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
All data can be shared after de-identifying individuals

When the data will become available and for how long
Access period starts after registration of results

To whom data/document is available
The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used
In order to achieve a treatment protocol for Bell's palsy patients and reduce the damage caused by facial paralysis

From where data/document is obtainable
emai:Mohammadrezasaadati1373@gmail.com

What processes are involved for a request to access data/document
After reviewing the request via email and providing the applicant's goals for the new study

Comments