

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the effect of high level laser in improving facial nerve function in patients with Bell's palsy

#### Protocol summary

##### Study aim

Determining the effect of high-power laser in improving facial nerve function in patients with Bell's palsy

##### Design

A clinical trial with a control group, with factorial groups, double-blind, randomized, 30 patients. SPSS statistical software was used for randomization.

##### Settings and conduct

In this study, patients are randomly divided into intervention and control groups, and the patients and the data analyst do not know which group each patient belongs to. Before the study, it is fully explained to the patients what the study is like and the satisfaction. This study is conducted in Amin Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with Bell's palsy symptoms  
2- At least one month has passed since receiving initial therapeutic interventions  
Non-entry criteria: 1- Patients with malignancy, high blood pressure, uncontrolled diabetes mellitus, brain and nerve diseases, simultaneous multiple cranial nerve palsy, pregnancy and breastfeeding. 2- Patients with a history of recurrent facial paralysis or facial deformity

##### Intervention groups

The intervention group receives high-power laser and exercise, and the control group receives only exercise.

##### Main outcome variables

Improving the function of the facial nerve in the electrodiagnostic study and the HBS system related to the facial nerve.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190618043931N3**

Registration date: **2023-10-02, 1402/07/10**

Registration timing: **prospective**

Last update: **2023-10-02, 1402/07/10**

Update count: **0**

##### Registration date

2023-10-02, 1402/07/10

##### Registrant information

###### Name

Shila Haghghat

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3627 5139

###### Email address

shila\_haghghat@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-12, 1402/07/20

##### Expected recruitment end date

2024-04-02, 1403/01/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of high level laser in improving facial nerve function in patients with Bell's palsy

##### Public title

High level laser in Bell's palsy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Patients with symptoms of Bell's palsy At least one

month has passed since receiving initial treatment interventions

**Exclusion criteria:**

Patients with malignancy, high blood pressure, uncontrolled diabetes mellitus, brain and nerve diseases, simultaneous multiple cranial nerve palsy, pregnancy and breastfeeding Patients with a history of recurrent facial paralysis or facial deformity

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: 30

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Referred patients are randomly divided into two intervention and control groups. In this way, each person is assigned a number and then they are entered into the study groups with the number randomization table. This randomization is without placement.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The data analyst is unaware of which group each patient was placed in.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Esfahan University of Medical Sciences

**Street address**

No.30,Taleghani Alley, East Hasht behesht Ave , Esfahan

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8157955891

**Approval date**

2022-01-19, 1400/10/29

**Ethics committee reference number**

IR.MUI.MED.REC.1400.750

**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**

Severity of facial nerve palsy in HBS system and electrodiagnostic study

**Timepoint**

At the beginning of treatment, 3 and 6 weeks after treatment

**Method of measurement**

HBS system and electrodiagnostic study

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: high-power laser with Fisioline device in 12 sessions with a wavelength of 1064 and a frequency of 500 Hz is performed in the path of the facial nerve and exercises related to the facial nerve are taught. Regarding eye exercises, the patient is told to look down. Then gently place the index finger behind the upper eyelid and keep the eye closed. And with the fingers of the other hand, pull the eyebrow up. This exercise prevents the eyelids from tightening. After that, the patient tries to close the eyelids. press each other. Also, after this movement, the patient closes his eyes as if he were looking at the sunlight, in other words, he brings both eyelids closer to each other. To exercise in the mouth area, the patient should smile in such a way that the lips are closed and he can use his fingers to equalize the location of the corners of the mouth on both sides. After some time, the patient should perform this movement without the help of fingers and for a longer time. Gradually, the patient should raise only one side of the mouth and then repeat this movement for the other side. For the movements of the mouth and cheek area, the patient should also perform movements such as whistling and blowing. To exercise in the nasal area, the patient should try to take a deep breath by opening the nostrils and keep the mouth closed during this movement. It is recommended to do the exercises three

times a day and each movement 5 times in Every turn should be done and exercises should be continued for 4 weeks.

**Category**

Rehabilitation

**2****Description**

Control group: exercises related to the facial nerve are taught. Regarding eye exercises, the patient is told to look down. Then gently place the index finger behind the upper eyelid and keep the eye closed. And with the fingers of the other hand, pull the eyebrow up. This exercise prevents the eyelids from tightening. After that, the patient tries to close the eyelids. press each other. Also, after this movement, the patient closes his eyes as if he were looking at the sunlight, in other words, he brings both eyelids closer to each other. To exercise in the mouth area, the patient should smile in such a way that the lips are closed and he can use his fingers to equalize the location of the corners of the mouth on both sides. After some time, the patient should perform this movement without the help of fingers and for a longer time. Gradually, the patient should raise only one side of the mouth and then repeat this movement for the other side. For the movements of the mouth and cheek area, the patient should also perform movements such as whistling and blowing. To exercise in the nasal area, the patient should try to take a deep breath by opening the nostrils and keep the mouth closed during this movement. It is recommended to do the exercises three times a day and each movement 5 times in Every turn should be done and exercises should be continued for 4 weeks.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Amin hospital

**Full name of responsible person**

Dr.Shila Haghighat

**Street address**

Sonbolestan Ave, Esfahan

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8148653141

**Phone**

+98 31 3445 5051

**Email**

amin@mui.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Gholamreza Asgari

**Street address**

Medical university of Esfahan , Hezar jerib Ave

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 8138

**Email**

askari@mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shila Haghighat

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

Alzahra hospital, Sofe Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3627 5139

**Fax**

**Email**

shila\_haghighat@med.mui.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shila Haghighat

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Email**

shila\_haghighat@med.mui.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shila Haghighat

**Position**

Assistant professor

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**Email**

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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 is potentially shareable after unidentifiable individuals

**When the data will become available and for how long**

2025

**To whom data/document is available**

Researchers working in universities and scientific centers

**Under which criteria data/document could be used**

no condition

**From where data/document is obtainable**

Shila\_haghighat @mui.ac.ir

**What processes are involved for a request to access data/document**

Send a request email and explain the purpose of using the data.

**Comments**