

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

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Isfahan

Postal code

8148653141

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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

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8174673461

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+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

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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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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Shila Haghighat

Position

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Latest degree

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Other areas of specialty/work

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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