Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Haghighat
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3627 5139
Email address
shila_haghighat@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

Isfehan

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
Isfehan

Postal code
8148653141

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+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
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Province
Isfehan

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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

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Person responsible for scientific inquiries

Contact

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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

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Full name of responsible person

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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