Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The efficacy of low level laser therapy in the treatment of Bell's palsy in diabetic patients

Protocol summary

Summary

In current single-blinded randomized clinical trial, 20 diabetic patients with Bell’s palsy aged greater than 18 years old, will be undergone treatment by low level laser therapy, to evaluate treatment efficacy. Pregnant patients, whom decline to undergo electromyography (EMG) or nerve conduction velocity (NCV) examinations, and patients suffering cancer, will be excluded. Patients will be examined in terms of facial nerve palsy grading and subsequently will undergo EMG and NCV tests, in order to evaluate muscles function (frontalis, orbicularis oris, orbicularis oculi) and axonal injury severity (frontalis, orbicularis oris, orbicularis oculi), respectively. Using sealed envelope method, patients will be randomly assigned to two groups: study group (10 patients) will receive 12 sessions of low level laser therapy during one month, where control group (10 patients) will not. At the end, patients will be worked up to evaluate recovery grade after treatment and one month later, by NCV and EMG tests. Neurologist who will perform EMG and NCV tests will be blinded to patients allocated group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011128545N2**
Registration date: **2017-01-20, 1395/11/01**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-01-20, 1395/11/01

Registrant information

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Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research and Development, Tabriz University of Medical Sciences

Expected recruitment start date

2017-02-01, 1395/11/13

Expected recruitment end date

2018-05-01, 1397/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of low level laser therapy in the treatment of Bell's palsy in diabetic patients

Public title

The efficacy of low level laser therapy in the treatment of Bell's palsy in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diabetic patients with Bell’s palsy aged greater than 18. exclusion criteria: pregnant patients; patients have not undergone electromyography or nerve conduction velocity; patients with history of epilepsy; patients with history of cancer; patients with impaired coagulation tests; patients who have heart pace maker.

Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Sealed envelope method used to randomize patients study groups allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Vice Chancellor for Research, Tabriz University of Medical Sceinces, Daneshgah square
City
Tabriz
Postal code
Approval date
2016-12-05, 1395/09/15
Ethics committee reference number
IR.TBZMED.REC.1395.926

Health conditions studied

1

Description of health condition studied
Bell Palsy
ICD-10 code
G51.0
ICD-10 code description
Facial palsy

Primary outcomes

1

Description
Axonal injury severity
Timepoint
before laser therapy, at the end of laser therapy, one month after laser therapy
Method of measurement
nerve conduction velocity (NCV) test

2

Description
Muscle function pattern
Timepoint
before laser therapy, at the end of laser therapy, one month after laser therapy
Method of measurement
electromyography (EMG)

Secondary outcomes

1

Description
patients bell palsy recovery
Timepoint
at the end of laser therapy, one month after laser therapy
Method of measurement
physical examination

Intervention groups

1

Description
Intervention group: during a one-month period in three sessions per week, low level laser therapy will be administered on totally 9 contact points (near stylomastoid foramen and route of facial nerve branches) for one minute, by low level laser diode with wavelength of 980 nm, frequency of 100 Hz and 5J energy density.
Category
Treatment - Other

2

Description
Control group: no intervention will be administered.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Solmaz Fakhari

Street address
Golgasht Street, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
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Alireza Ostadrahimi
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Vice chancellor for research, Tabriz University of Medical Sceinces, Daneshgah square
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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
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty