

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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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 Sciences, 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

Full name of responsible person

Alireza Ostadrahimi

Street addressVice chancellor for research, Tabriz University of
Medical Sciences, Daneshgah square**City**

Tabriz

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****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Solmaz Fakhari

Position

Assistant Professor, Specialist in Anesthesiology

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Full name of responsible person

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Web page address**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*