

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effects of low level laser therapy and LED on inferior alveolar nerve regeneration or recovery after sagittal split osteotomy of mandible

Protocol summary

Summary

Purpose: In this study, we investigated the effect of Low Level Laser Therapy (LLT) and Light-Emitting Diode (LED) on Inferior Alveolar Nerve regeneration/recovery after bilateral sagittal split osteotomy. Design: In this double-blinded study we considered 20 patients with Inferior Alveolar Nerve injury after bilateral sagittal split osteotomy of the mandible at Taleghani Hospital as study population. Patients were randomized into two equal groups: control and intervention. Inclusion Criteria: Inferior Alveolar nerve injury after bilateral sagittal split osteotomy (Neurapraxia, Sanderland I, II). Exclusion Criteria: Neurosensory disturbance, taking antipsychotic drugs, previous facial bone fracture, bad split, inferior alveolar nerve injury more than Neurapraxia. Intervention: 10 patients were given LLLT and LED. Emitting Low Level Laser and LED on inferior alveolar nerve of intervention group was done during 6 sessions (24 hours, 2 days, 3 days, 7 days, 14 days and 28 days after surgery). Primary outcome variable: Neurosensory deficit . Secondary outcome variable: Neurosensory Recovery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015053022471N2**

Registration date: **2015-08-15, 1394/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-15, 1394/05/24

Registrant information

Name

Mehdi Bemanali

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-08-30, 1393/06/08

Expected recruitment end date

2014-10-30, 1393/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of low level laser therapy and LED on inferior alveolar nerve regeneration or recovery after sagittal split osteotomy of mandible

Public title

Effects of photo therapy on neurosensory disturbance of the chin.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: Nerve injures after Bilateral sagittal Split Osteotomy (sanderlandII,II) Exclusion: neurosensory deficit; precedent headache; retardation; neurologic disorder; collagen or vascular disease; previous facial fracture;type 1 diabetes ; bad split; genioplasty

Age

From **20 years** old to **29 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)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Sciences (Vice-Chancellor in International Affairs)

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Shahid Arabi St, Yaman St, Shahid Chamran Exp, Tehran

City

Tehran

Postal code

Iran

Approval date

2014-10-12, 1393/07/20

Ethics committee reference number

1000/683 (Vice- Chancellor in International Affairs)

Health conditions studied**1****Description of health condition studied**

Neruserosory deficit after Orthognathic surgery

ICD-10 code

Z09.0

ICD-10 code description

Follow-up examination after surgery for other conditions

Primary outcomes**1****Description**

Nerosensory deficit

Timepoint

preoperative, 1 day , 3days , 7 days , 14 days, 2 months, 6 months after surgery

Method of measurement

Examination

Secondary outcomes**1****Description**

Nerosensory Recovery

Timepoint

preoperative, 1 day , 3days , 7 days , 14 days, 2 months, 6 months after surgery

Method of measurement

Examination

Intervention groups**1****Description**

Intervention: Emitting Low Level Laser and LED on inferior alveolar nerve during 6 sessions (24 hours, 2 days, 3 days, 7 days, 14 days and 28 days after surgery)

Category

Rehabilitation

2**Description**

Control: No intervention

Category

N/A

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

Taleghani Hospital

Full name of responsible person

Mehdi Bemanali

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Taleghani Hospital, Shahid Arabi St., Yaman St., Chamran Exp, Tehran

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

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Full name of responsible person

Dr. Seyyed Hassan Mohajerani

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Chamran Exp, Tehran**City**

Tehran

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

Yes

Title of funding source

Shahid Beheshti 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**

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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*