

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Photobiomodulation on Neurosensory Disturbance Recovery after Maxillofacial Trauma

Protocol summary

Study aim

Assessment of low level laser therapy (LLLT) on neurosensory recovery in lower face region after maxillofacial trauma; assessment of low level laser therapy (LLLT) on neurosensory recovery in midfacial area after maxillofacial trauma

Design

Two arm parallel group randomised double blind clinical trial. Randomization is done with statistical software. All patients with bilateral facial injury will participate in this study. Affected sides will be randomly divided into case or control groups.

Settings and conduct

All patients with maxillofacial trauma referred to AJA University of Medical Sciences will be included. Patients and researcher will be kept blind in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with neurosensory disturbance following maxillofacial trauma Non-inclusion criteria: -

Intervention groups

Applying low-level laser radiation on one affected site (for example right side) and no radiation (turned off device) on the contralateral affected side (left side)

Main outcome variables

Improvement of sensory deficit after LLL radiation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190916044784N1**

Registration date: **2019-10-11, 1398/07/19**

Registration timing: **prospective**

Last update: **2019-10-11, 1398/07/19**

Update count: **0**

Registration date

2019-10-11, 1398/07/19

Registrant information

Name

Shahryar Bashirigoudarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4415 7941

Email address

dr.s.bashiri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Photobiomodulation on Neurosensory Disturbance Recovery after Maxillofacial Trauma

Public title

The Effect of Photobiomodulation on Neurosensory Disturbance Recovery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with bilateral neurosensory disturbance after maxillofacial trauma

Exclusion criteria:

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization via statistical software (Random Allocation Software) and affected side will be settled into case or control group

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and researcher -that is in charge of clinical part- are blinded in this study. The data from clinical intervention sessions will be sent to data collection assistant by code.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
AJA University of Medical Sciences

Street address
Unit 27, No 14, South Laleh street, West Ferdos Boulevard, Tehran

City
Tehran

Province
Tehran

Postal code
1484977554

Approval date
2019-09-15, 1398/06/24

Ethics committee reference number
IR.AJAMS.REC.1398.136

Health conditions studied

1

Description of health condition studied
Neurosensory deficit after maxillofacial trauma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Neurosensory improvement after trauma in facial area

Timepoint
Before intervention, 4 weeks after intervention, 8 weeks after intervention, 12 weeks after intervention

Method of measurement
Visual Analogue Scale, Two point discrimination test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: LLL radiation in one affected site

Category
Rehabilitation

2

Description
Control group: LLL radiation to contralateral affected side while the device is turned off (placebo effect)

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
AJA University of Medical Sciences

Full name of responsible person
Shahryar Bashiri

Street address
AJA university of Medical Sciences, North Kargar St, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1411718541

Phone
+98 21 8609 6350

Email
aja@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Shahryar Bashiri

Street address

AJA University of Medical Sciences, North Kargar St,
Tehran. Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

info@aja.ac.ir

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

Yes

Title of funding source

Artesh University of Medical Sciences

Proportion provided by this source

50

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**

Artesh University of Medical Sciences

Full name of responsible person

Shahryar Bashiri

Position

Oral and Maxillofacial Surgeon

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Unit 27, No 14, South Laleh street, West Ferdos
Boulevard, Tehran

City

Tehran

Province

Tehran

Postal code

1484977554

Phone

+98 21 4415 7941

Email

dr.s.bashiri@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Shahryar Bashiri

Position

Oral and Maxillofacial Surgeon

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Unit 27, No 14, South Laleh street, West Ferdos
Boulevard, Tehran

City

Tehran

Province

Tehran

Postal code

1484977554

Phone

+98 21 4415 7941

Email

dr.s.bashiri@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Shahryar Bashiri

Position

Oral and Maxillofacial Surgeon

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Unit 27, No 14, South Laleh street, West Ferdos
Boulevard, Tehran

City

Tehran

Province

Tehran

Postal code

1484977554

Phone

+98 21 4415 7941

Email

dr.s.bashiri@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information is available.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable