

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Leukocyte Platelet-rich Fibrin And Low level laser on acceleration of neurosensory recovery following Genioplasty

Protocol summary

Study aim

Effect of photo-biomodulation on recovery from neurosensory disturbances after genioplasty and LPRF insertion

Design

Triple blind randomized split mouth clinical trial for patients who are candidates for genioplasty . One side was designated as a intervention side (accidentally chosen by computer) and the other as the control side. On the control side, the laser probe will be turned off and will be placed on the designated area. To asses neurosensory recovery , five subjective and objective tests will be used included visual analog scales (VAS) for general sensitivity, directional discrimination, two point discrimination, pain discrimination and thermal discrimination 1-14-28-56 days post surgery by a clinician unaware of laser therapy.

Settings and conduct

Triple blind randomized split mouth clinical trial for patients who are candidates for genioplasty referred to Laleh hospital, Tehran, Iran, from July 2023 to August 2023. Surgical approach: The procedure will be performed under general anesthesia. Then LPRF will be fixed by vicryl 4-0 sutures around bilateral mental nerves.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients needed genioplasty.
Exclusion criteria: Patients with history of previous trauma to mandible and chin region or mental nerve; History of previous BSSO or Genioplasty ;Patients who do not agree to participate the research.

Intervention groups

Photo-biomodulation therapy will be performed immediately post surgery and 4-6 weeks (twice weekly). On the control side, the laser probe will be turned off on the designated area. To asses neurosensory recovery , five tests will be performed on 1-14-28-56 days post surgery by a clinician unaware of laser therapy.

Main outcome variables

It is proposed that neurosensory disturbances on control and intervention sides will be different.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230619058536N1**

Registration date: **2023-07-06, 1402/04/15**

Registration timing: **prospective**

Last update: **2023-07-06, 1402/04/15**

Update count: **0**

Registration date

2023-07-06, 1402/04/15

Registrant information

Name

Parsa Behnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2242 6454

Email address

parsabehnia1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-11, 1402/04/20

Expected recruitment end date

2023-08-11, 1402/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Leukocyte Platelet-rich Fibrin And Low level laser on acceleration of neurosensory recovery following Genioplasty

Public title

Comparison of Leukocyte Platelet-rich Fibrin And Low level laser on acceleration of neurosensory recovery following Genioplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient who are candidate for genioplasty

Exclusion criteria:

Patients who have a history of trauma in the mandible area, especially in the chin area They were previously subjected to similar orthognathic surgery (SSO or Genioplasty). Obvious nerve damage occurs during surgery or the nerve is not identified during surgery. Patients who use psychiatric drugs. People who do not want to participate in the study. Nerve damage has occurred in the past for other reasons.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

One side of the mandible is designated as intervention side and the other as the control side ,in the first patient right side will be chosen as intervention side and this will be continued in every other patient.

Blinding (investigator's opinion)

Triple blinded

Blinding description

On the control side, the laser probe will be turned off and will be placed on the designated area; the device will not be activated, so patients will not be aware of which side will being radiated by laser. neurosensory evaluation will be performed by a person who is not aware of which side the laser will be radiated.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of AJA University of Medical Sciences

Street address

No. 3, 21 St, Velenjak Ave

City

Tehran

Province

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Postal code

1985878354

Approval date

2023-05-15, 1402/02/25

Ethics committee reference number

IR.AJAUMS.REC.1402.028

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

Trauma to mental nerve (following genioplasty)

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

To asses post trauma (genioplasty) neurosensory recovery of mental nerve

Timepoint

1-14-28-56 days post surgery by a clinician unaware of laser therapy.

Method of measurement

To asses neurosensory recovery , five subjective and objective tests will be used included Visual Analog Scales (VAS) for general sensitivity, directional discrimination, two point discrimination, pain discrimination and thermal discrimination

Secondary outcomes

empty

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

Intervention group: Photo-biomodulation therapy will be performed immediately post surgery and 4-6 weeks (twice weekly).

Category

Rehabilitation

2

Description

Control group: On the control side, the laser probe will be turned off and will be placed on the designated area.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Laleh hospital

Full name of responsible person

Parsa Behnia

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1467684595

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr Reza Fekrazad

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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

Artesh University of Medical Sciences

Proportion provided by this source

10

Public or private sector

Private

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

Parsa Behnia

Position

Post-graduate student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data**Contact****Name of organization / entity**

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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

The data of all of the main variables of the split mouth designed research can be shared.

When the data will become available and for how long

6 months post publication the data may be released.

To whom data/document is available

Data will be shared with all researchers.

Under which criteria data/document could be used

Correct citation of the shared data and the name of all researchers in the future research using the data .

From where data/document is obtainable

Dr Parsa Behnia Cell phone : 09122979748 Address :
No.3 , 21 St , Velenjak , Tehran , Iran 1985878354
parsabehnia1@gmail.com

What processes are involved for a request to access data/document

Sending a legal email.

Comments