

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Comparison of pain perception and tissue repair after frenectomy with surgical blade and 445 nm and 970 nm diode laser: a clinical trial study

Protocol summary

Registration timing: **prospective**

Study aim

Comparison of pain perception and tissue repair after frenectomy with surgical blade and 445 nm and 970 nm diode laser

Last update: **2022-10-29, 1401/08/07**

Update count: **0**

Registration date

2022-10-29, 1401/08/07

Design

Clinical trial with a control group with parallel group, with blinding of only outcome assessment and data collection, randomized with Random Allocation Software using 29 block on 174 patients

Registrant information

Name

Aryousha Moallemsavasari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

The study will be carried on in the dental clinic of Mazandaran University of Medical Sciences. 174 participants will be allocated to three groups using blocks of 6 with Random Allocation Software. Assessments will be performed by a blinded individual immediately after surgery, 7, 14 and 28 days after surgery. Data collection will also be performed by a blinded researcher and the data will be concealed and sent to the statistician for analysis. Results will be provided to the blind writer of the draft, who will in turn compose the draft and share it with all the researchers to edit and provide the final manuscript.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Need of frenectomy surgery in orthodontic treatment, not undergoing speech therapy, periodontal therapy and prosthetic treatment in anterior maxilla

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group 1: 445 nm diode laser Intervention group 2: 970 nm diode laser Control group: scalpel

Main outcome variables

Post-operative pain and tissue healing

Scientific title

Comparison of pain perception and tissue repair after frenectomy with surgical blade and 445 nm and 970 nm diode laser: a clinical trial study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220630055326N1**

Registration date: **2022-10-29, 1401/08/07**

Public title

Comparison of 445 nm and 970 nm diode lasers and surgical blade in frenectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Need for orthodontic treatment Need for labial frenectomy

Exclusion criteria:

Undergoing speech therapy Undergoing periodontal therapy Undergoing prosthetic treatment in anterior maxilla

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **174**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be divided into 29 blocks of 6 and then allocated to one of the three groups of the study using Random Allocation Software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moallem Sq.

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2022-10-08, 1401/07/16

Ethics committee reference number

IR.MAZUMS.REC.1401.338

Health conditions studied

1

Description of health condition studied

Dental diastema and high labial frenum

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Postoperative pain

Timepoint

Immediately after the surgery, 7 days, 14 days and 28 days after the surgery

Method of measurement

Visual Analogue Scale questionnaire

2

Description

Postoperative wound healing

Timepoint

Immediately after the surgery, 7 days, 14 days and 28 days after the surgery

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 445 nm diode laser

Category

Treatment - Surgery

2

Description

Intervention group 2: 970 nm diode laser

Category

Treatment - Surgery

3

Description

Control group: scalpel

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghban Dental Clinic

Full name of responsible person

Abbas Mesgarani

Street address

Baghban Dental Clinic, Khazar Blvd.

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Mazandaran

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4816895471

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dentistry@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram Ebrahimnejad

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Deputy of Research and Technology of Mazandaran
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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

Mazandaran University of Medical Sciences

Proportion provided by this source

100

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

Mazandaran University of Medical Sciences

Full name of responsible person

Farhad Sobouti

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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farhad_sobouti@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Sepideh Dadgar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Aryousha Moallem Savasari

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information about the main outcomes of the study and their relationship with the variables of the study will be published after anonymizing the data.

When the data will become available and for how long

The access period will start 3 months after the results are published.

To whom data/document is available

Researchers working in universities, institutes and scientific centers and people working in related industries can apply to receive the data.

Under which criteria data/document could be used

The use of data for the purpose of independent analysis is unimpeded, but any activity leading to the publication using the data is subject to obtaining explicit permission.

From where data/document is obtainable

In order to receive data, it is necessary to send a request to the first author of the article, Aryousha Moallem Suvasri, via the email address a.moallem@mazums.ac.ir or aaryoosha@gmail.com. If needed, call +989112561042.

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

The request received via e-mail will be read and considered within two working days, and negotiations will begin to coordinate and ensure that the applicant meets the conditions by the same time. It is expected to take no more than seven working days to send the documents to the applicant.

Comments