Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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

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

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.

Participants/Inclusion and exclusion criteria
Need of frenectomy surgery in orthodontic treatment, not undergoing speech therapy, periodontal therapy and prosthetic treatment in anterior maxilla

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220630055326N1**
Registration date: **2022-10-29, 1401/08/07**
Registration timing: **prospective**

Last update: **2022-10-29, 1401/08/07**
Update count: **0**

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

Registrant information
Name
Aryousha Moallemsavasari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 3320 7729
Email address
a.moallem@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

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

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

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.

City
Sari

Province
Mazandaran

Postal code
4816895471

Phone
+98 11 3324 4894

Email
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

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

City
Sari

Province
Mazandaran

Postal code
4815733971

Phone
+98 11 3325 7230

Fax
+98 11 3326 1244

Email
pajoheshi@mazums.ac.ir

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

Street address
Baghban Dental Clinic, Khazar Blvd.

City
Sari

Province
Mazandaran

Postal code
4816895471

Phone
+98 11 3324 4894

Email
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

Street address
Baghban Dental Clinic, Khazar Blvd.

City
Sari

Province
Mazandaran

Postal code
4816895471

Phone
+98 11 3324 4894

Email
dadgar_sepideh@yahoo.com

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
Street address
No. 4, Gol-e Sorkh Bldg., 13th Alley, Mahdiye St.
City
Sari
Province
Mazandaran
Postal code
4818897388
Phone
+98 11 3320 7728
Email
aaryoosha@gmail.com

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