

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of Complications and Patients' Satisfaction using Diode laser versus Conventional Technique in Labial Frenectomy

Protocol summary

Study aim

Comparison of Complications and Patients' Satisfaction using Diode laser versus Conventional Technique in Labial Frenectomy

Design

Clinical trials with control group, with parallel groups, randomized, without control with placebo, single center trial. Sample size was 20 patients (2 groups of 10 control and intervention).

Settings and conduct

Faculty of Dentistry, Semnan University of Medical Sciences. The two study groups will undergo frenectomy surgery. Intervention group: By laser diode method
Control group: By conventional surgery method

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between 18 to 40 years old are admitted; patients who need labial Frenectomy treatment. Exclusion criteria: Present of systemic diseases; Present of diabetes; Present of immunodeficiency; Taking aspirin; Present of scleroderma; Addiction; History of delayed wound healing.

Intervention groups

Intervention group: Patients undergo frenectomy according to the protocol using diode laser. First we numb the area. Then hold the top and bottom of the phrenom with the help of two hemostats. With the help of a diode laser, extra tissue is cut. The surgical area will be covered by CO-PAK periodontal dressing. Control group: Patients underwent frenectomy according to the protocol standard surgical procedure. First we numb the area. Using a coronal razor number 15, extra tissue is cut. Then the incision with a suture 0.3 silk, We stitch.

Main outcome variables

Bleeding severity measure; Satisfaction and pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042679N1**

Registration date: **2020-02-11, 1398/11/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-11, 1398/11/22**

Update count: **0**

Registration date

2020-02-11, 1398/11/22

Registrant information

Name

Hanieh Raz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3333 7747

Email address

raz_hanie@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Complications and Patients' Satisfaction using Diode laser versus Conventional Technique in Labial Frenectomy

Public title
Evaluation of Diode Laser in Frenectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients between 18 to 40 years old are admitted.
 patients who need labial Frenectomy treatment.
Exclusion criteria:
 Present of systemic diseases Present of diabetes Present of immunodeficiency Taking aspirin Present of scleroderma Addiction History of delayed wound healing

Age
From **18 years** old to **40 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
Patients are allocated randomly with simple sequential allocation in one of the two study groups by help of sealed envelope and receive the intervention of the same group. The unit of randomization is patient. Sealed envelopes are delivered to expert. With each patient's visit, one of the envelopes is randomly selected by the patients and determines the study group. The stratification approach is not used.

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 Semnan University of Medical Sciences

Street address

Vice chancellor for research, Semnan University of Medical Sciences building, Basij Blvd

City

Semnan

Province

Semnan

Postal code

3519697344

Approval date

2019-11-02, 1398/08/11

Ethics committee reference number

IR.SEMUMS.REC.1398.189

Health conditions studied

1

Description of health condition studied

Labial frenectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bleeding severity measure

Timepoint

One week and one month after surgery

Method of measurement

The intensity of bleeding will be recorded with a rating of 0 to 5

2

Description

Satisfaction and pain

Timepoint

One week and one month after surgery

Method of measurement

Visual Analogue Scale (VAS) -10cm

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients undergo frenectomy according to the protocol using diode laser. First we numb the area. Then hold the top and bottom of the phrenom with the help of two hemostats. With the help of a diode laser, extra tissue is cut. The surgical area will be covered by CO-PAK periodontal dressing.

Category

Treatment - Surgery

2

Description

Control group: Patients underwent frenectomy according to the protocol standard surgical procedure. First we numb the area. Using a coronal razor number 15, extra tissue is cut. Then the incision with a suture 0.3 silk, We stitch.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Oral, Maxillofacial Dentistry, Faculty of Dentistry, Semnan University of Medical Scie

Full name of responsible person
Hanieh Raz

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Faculty of Dentistry, Semnan University of Medical Sciences, Hefdah Shahrivar St., Saadi Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Parviz Kokhaei

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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
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Hanieh Raz

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Maryam Jalili Sadrabaad

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

Some of the data is shared, such as information about
the main outcome

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific
institutions

Under which criteria data/document could be used

For re-study or scientific use

From where data/document is obtainable

Hanieh Raz raz_hanie@yahoo.com

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

Send an email containing the request for access to the
study and the type of study use with the applicant's
specification Check email Send data

Comments