

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Assesment of rotated teeth relapse after orthodontic treatment via fibrotomy with scalpel and diode laser: A Randomized clinical trail

Protocol summary

Study aim

Determining the recurrence rate, patient's pain, pocket depth and gingival resorption after treatment of rotated teeth with fibrotomy with surgical razor alone, surgical razor and low power laser, diode laser alone, diode laser with low power laser and low power laser alone. one month later. Comparison of recurrence rate, patient's pain and pocket depth after treatment of rotated teeth with 5 different ways

Design

Clinical trial with control group, with parallel groups (6 groups in total), one-side blinded, randomized, on 90 patients. Random allocation process is performed with random allocation software.

Settings and conduct

The place is in the office of orthodontists. The data recorder, researcher and statistician goes blind

Participants/Inclusion and exclusion criteria

Patients undergoing fixed orthodontic treatment who were 15 to 30 years old at the beginning of treatment and had rotated teeth and are now at the end of their fixed treatment should have a rotation rate of 20 to 70 degrees. No systemic disease, gingivitis and periodontitis, proximal and deep caries, developmental and anatomical malformations, use of drugs that disrupt bone metabolism, conditions in which the use of lasers is prohibited, such as pregnancy. Patients should have good oral hygiene and plaque index under 10%

Intervention groups

fibrotomy with 1.surgical razor alone, 2.surgical razor and low power laser, 3.diode laser alone, 4.diode laser with low power laser, 5.low power laser alone 6.control group

Main outcome variables

Arch relapse rate; Depth of gingival sulcus; Depth of probing around the tooth; The amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210621051653N1**

Registration date: **2021-08-04, 1400/05/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-04, 1400/05/13**

Update count: **0**

Registration date

2021-08-04, 1400/05/13

Registrant information

Name

Hanieh Rohaninezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3452 5770

Email address

hanieh.rohaninezhad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-28, 1400/05/06

Expected recruitment end date

2021-09-28, 1400/07/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment of rotated teeth relapse after orthodontic treatment via fibrotomy with scalpel and diode laser: A Randomized clinical trail

Public title

Assesment of rotated teeth relapse after orthodontic treatment via fibrotomy with scalpel and diode laser: A Randomized clinical trail

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing fixed orthodontic treatment who were 15 to 30 years old at the beginning of treatment and had rotated teeth and are now at the end of their fixed treatment should have a rotation rate of 20 to 70 degrees. Absence of systemic disease Absence of gingivitis and periodontitis, good oral hygiene, plaque index below 10% Absence of proximal caries and deep caries in the area of cementoamel junction (CEJ), absence of evolutionary and anatomical deformities Do not take drugs that disrupt bone metabolism Lack of conditions in which the use of lasers is prohibited, such as pregnancy

Exclusion criteria:

Teeth with periodontitis Tooth rotations greater than 70 degrees and less than 20 degrees Teeth with proximal caries or caries extending to the cementoamel junction (CEJ) Taking drugs that affect bone metabolism

Age

From **15 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

From the samples with inclusion criteria, 90 rotated teeth are selected by the census. After recording the demographic information of patients, including age, sex, location, contact number, etc., using the blocking method, these 90 teeth will be assigned to six groups. The random allocation process will be done with Random allocation software. With this software, 15 six-block blocks are selected and the samples are divided into six groups based on these blocks. This is a one-sided blind study in which the person recording the rate of rotation and pain and the statistician do not know who is in which group and are not aware of the type of treatment. The patient and the treating specialist are aware of the treatment used and cannot be blinded.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a one-sided blind study in which the person recording the rate of rotation and pain and the statistician do not know who is in which group and are not aware of the type of treatment. The patient and the treating specialist are aware of the treatment used and cannot be blinded.

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 Science

Street address

Narenj alley , Panzdah Khordad Ave

City

Sari

Province

Mazandaran

Postal code

4818865454

Approval date

2021-07-11, 1400/04/20

Ethics committee reference number

IR.MAZUMS..REC.1400.9105

Health conditions studied

1

Description of health condition studied

The rate of relapse after orthodontic treatment with fibrotomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The rate of relapse after orthodontic treatment with fibrotomy

Timepoint

The beginning of the study, one month after starting treatment

Method of measurement

Digimizer image analysis software

Secondary outcomes

1

Description

Depth of gingival sulcus

Timepoint

The beginning of the study, one month after treatment

Method of measurement

Using a periodontal probe

2

Description

Depth of probing around the teeth

Timepoint

The beginning of the study, one month after treatment

Method of measurement

Using a periodontal probe

3

Description

The amount of pain

Timepoint

The beginning of the study, one month after treatment

Method of measurement

VAS scale

Intervention groups

1

Description

Intervention group: Fibrotomy with a surgical razor

Category

Treatment - Devices

2

Description

Intervention group: Low power laser fibrotomy only (by Biolase EPIC X laser diode USA, wavelength 940 nm)

Category

Treatment - Devices

3

Description

Intervention group: Laser Fibrotomy with Surgical Laser Alone (Biolase EPIC X Laser Diode USA)

Category

Treatment - Devices

4

Description

Intervention group: Fibrotomy with Laser surgery combined with low power laser

Category

Treatment - Devices

5

Description

Intervention group: Perform fibrotomy first and then low power diode laser radiation

Category

Treatment - Devices

6

Description

Control group: without interfering

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Private orthodontic office

Full name of responsible person

Hanieh Rohaninezhad

Street address

Sadaf Department, Panzdah khordad Ave, Sari Town

City

Sari

Province

Mazandaran

Postal code

4851648573

Phone

+98 11 3326 3345

Email

hanieh.rohaninezhad@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Farah abad

City

Sari

Province

Mazandaran

Postal code

Phone

+98 11 3304 4000

Email

ict@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

70

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

avideh maboudi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Panzdah khordad Ave

City

Sari

Province

Mazandaran

Postal code

4818865454

Phone

+98 11 3326 3345

Email

Avideh48188@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Avideh Maboudi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Panzdah khordad Ave

City

Sari

Province

Mazandaran

Postal code

4818865454

Phone

+98 11 3326 3345

Email

Avideh48188@yahoo.com

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

Mazandaran University of Medical Sciences

Full name of responsible person

Avideh Maboudi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Panzdah khordad Ave

City

Sari

Province

Mazandaran

Postal code

4818865454

Phone

+98 11 3326 3345

Email

Avideh48188@yahoo.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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data file of the participants will generally be sent along with the submission of the research article after being unidentifiable The study protocol will be fully explained in the text of the article The cases and map of statistical analysis and the results that need to be mentioned in the text of the article are given Patients' informed consent form must be published as an attachment The report of what will be seen in the clinic will be mentioned as results in the text of the article.

When the data will become available and for how long

From 2021 to one year after the publication of the results

To whom data/document is available

Journal Referees. Anyone who intends to conduct further studies in this field will receive the documentation by sending an email to the responsible author.

Under which criteria data/document could be used

People who want to do further studies in this field. There is no obstacle

From where data/document is obtainable

corresponded author Avidéh Maboudi

Avidéh48188@yahoo.com

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

It does not take much time. It may take up to a week to send you an email right after we receive it

Comments