

# 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

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**Postal code**

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**Phone**

+98 11 3326 3345

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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**

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**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**

Avideh Maboudi

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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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 Avidah Maboudi

Avidah48188@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**