

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### **Determining the effectiveness of various gingival retraction techniques included cord,paste,laser on the periodontal indicators ,after impression in fixed prosthesis:a randomized clinical trial study**

#### **Protocol summary**

##### **Study aim**

Determining the effectiveness of various gingival retraction techniques included cord,paste,laser on the rate of bleeding,inflammation and gingival resorption and periodontal plaque,after impression in fixed prosthesis

##### **Design**

In this Randomized Triple blinded Clinical trial study, 60 patients with maxillary and mandibular first molar in need of crown reconstruction that have inclusion criteria and visit the prosthodontist's clinic in Kermanshah are randomly assigned to intervention groups.

##### **Settings and conduct**

Teeth in need of crown reconstruction are randomly divided into 3 intervention groups. clinical treatment is done by a prosthodontist with 10 years of work experience in a dental clinic. one of gingival retraction techniques used for each group of patients. Patients were followed after 7 and 14 days by another prosthodontists and student. In this triple blinded study, only the prosthodontist who insert the restorations knows about the groups and participants, outcome evaluators and result analyst were blinded.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: Patients who need their maxillary or mandibular first molar to be restored; have the opposite teeth in functional occlusion and at least one proximal contact with the adjacent teeth; have clinical sulcus depth between 2-3 mm and thick gingiva biotype; no smoking; acceptable oral hygiene and periodontally healthy (plaque index and bleeding on probing had to be below 20% previously to the prosthodontic treatment);.ready to take part in the study and sign the testimonial. Exclusion criteria: have previous periodontal surgery; have mobility in tooth; use drugs having effect on periodontium; patients have systemic disease.

##### **Intervention groups**

1.gingival retraction with cord 2.gingival retraction with paste 3.gingival retraction with laser

##### **Main outcome variables**

Recession; plaque index; gingival index; bleeding index

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20160213026538N6**

Registration date: **2021-01-07, 1399/10/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-01-07, 1399/10/18**

Update count: **0**

##### **Registration date**

2021-01-07, 1399/10/18

##### **Registrant information**

##### **Name**

Hedaiat Moradpoor

##### **Name of organization / entity**

Kermanshah University of Medical Sciences

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 83 3729 6910

##### **Email address**

h.moradpour@kums.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2021-01-02, 1399/10/13

##### **Expected recruitment end date**

2021-05-03, 1400/02/13

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Determining the effectiveness of various gingival retraction techniques included cord,paste,laser on the periodontal indicators ,after impression in fixed prosthesis:a randomized clinical trial study

**Public title**

Determining the effectiveness of various gingival retraction techniques included cord,paste,laser

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients who need their maxillary or mandibular first molar to be restored have the opposite teeth in functional occlusion and at least one proximal contact with the adjacent teeth have clinical sulcus depth between 2-3 mm and thick gingiva biotype dont be a smoker Acceptable oral hygiene and periodontally healthy(plaque index and bleeding on probing had to be below 20% previously to the prosthodontic treatment) ready to take part in the study and sign the testimonial

**Exclusion criteria:**

have previous periodontal surgery have mobility in tooth use drugs having effect on periodontium patients have systemic disease

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Based on the random allocation law, after determining 60 maxillary and mandibularfirst molars based on statistical calculations, 20 cards for the cord group and 20 cards for paste group and 20 cards for laser group will be placed in a draw glass, then the cards will be dropped out randomly and without replacement and the resulting sequence will be recorded.Then,60 envelopes are prepared and each random sequence created is recorded on a card and the cards are inserted into the envelope respectively. In order to maintain a random sequence, the envelopes are numbered to the same. In the end, the door covers are enclosed in boxes and placed in a box respectively. At the time of the start of the registration of

the participants, according to the order of entry of qualified participants to study, one of the envelopes are opened in sequence and the participant's assigned group is revealed

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

in this clinical trial study, only the prosthodontist who do gingival retraction techniques knows about the groups and the outcome evaluators(other prosthodontist and the calibrated examiner) are blind to the assignment of each participant in each of the study groups. Participants in the study are blind toward their own group when they are aware of the similar costs and benefits of clinical treatments based on studies. Also the result analyst, have no information about the data of each group.It should be mentioned as the retraction have no differences in appearance after do ,double blinding is available.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Kermanshah University of Medical Sciences

**Street address**

Ethics Committee, Department of Research and Technology, Central Building, Shahid Beheshti Boulevard, Kermanshah

**City**

kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2020-12-22, 1399/10/02

**Ethics committee reference number**

IR.KUMS.REC.1399.878

**Health conditions studied****1****Description of health condition studied**

Gingival retraction; impression in fixed prosthesis

**ICD-10 code****ICD-10 code description**

## Primary outcomes

### 1

**Description**

recession

**Timepoint**

after one and two week

**Method of measurement**

scanned reference on first session

### 2

**Description**

gingival index

**Timepoint**

at the first session, after one and two week

**Method of measurement**

gingival index

### 3

**Description**

plaque index

**Timepoint**

at the first session, after one and two week

**Method of measurement**

plaque index

### 4

**Description**

bleeding index

**Timepoint**

at the first session, after one and two week

**Method of measurement**

bleeding index

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: retraction gingiva with paste

**Category**

Treatment - Other

### 2

**Description**

Intervention group: retraction gingiva with laser

**Category**

Treatment - Other

### 3

**Description**

Intervention group: retraction gingiva with cord

**Category**

Treatment - Other

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Dr Moradpour Dental clinic

**Full name of responsible person**

Hedaiat Moradpour

**Street address**

Dabiraezam st.

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6713739988

**Phone**

+98 83 3729 6910

**Email**

hedaiat.mpradpour@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Reza Khodarahmi

**Street address**

Vice Chancellor for Research and Technology,  
Kermanshah University of Medical Sciences, Shahid  
Beheshti Blvd

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3838 4185

**Email**

rkhodarahmi@kums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Ali Naeemi  
**Position**  
Under graduated student of Dentistry  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
The school of Dentistry, shariati St.  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
67139546581  
**Phone**  
+98 83 3727 7030  
**Email**  
alinaeemi420@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Hedaiat Moradpoor  
**Position**  
Associate professor of Prosthodontics department  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Department of Prosthodontics, The School of  
Dentistry, Kermanshah University of Medical Sciences,  
Shariati St.  
**City**  
kermanshah  
**Province**  
Kermanshah  
**Postal code**  
67139546581  
**Phone**

+98 83 3729 6910

**Fax**  
+98 83 3729 1335

**Email**  
h.moradpour@kums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Ali Naeemi  
**Position**  
Under graduated student of Dentistry  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
The school of Dentistry, Kermanshah University of  
Medical Sciences, Shariati St.  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
67139546581  
**Phone**  
+98 83 3727 7030  
**Email**  
alinaeemi420@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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