# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Evaluation of the effect of gingival retraction with laser and retraction cord on marginal adaptation and gingival recession in full ceramic crowns for first premolar of maxilla – a clinical trial study

## Protocol summary

**Study aim**

Evaluation of the effect of gingival retraction with laser and retraction cord on marginal adaptation and gingival recession

**Design**

Clinical trial, with parallel groups, one-way blind, randomized, on 20 patients. Randomization with Excel software was used.

**Settings and conduct**

Patients are visited in the dental office. Part of the work is done in the research center laboratory.

**Participants/Inclusion and exclusion criteria**

entry conditions: Good general health(The patient has no systemic disease that can affect clinical outcomes) Periodontal health(Plaque index and BOP should be below 20% before prosthetic treatment) There is a good keratinized gum around the abutment tooth (gingival biotype is thick). It should not have obvious signs and symptoms of bruxism or clenching abutment teeth need reconstruction Non-living abutment teeth that have a positive long-term prognosis based on clinical evaluations and radiology Have sufficient periodontal support teeth for single-unit restoration and also have a minimum of looseness The teeth have sufficient preparation length to ensure retention and resistance shapes The patient is willing to participate in our study and sign the consent form. No entry conditions: The patient is unwilling or unable to observe adequate oral hygiene (index plate and BOP should be below 20%). Basic teeth have clinical signs. Have loose teeth of second or more degrees. Teeth need periodontal surgery before preparing the veneer. Parafunctional habits Periodontitis, severe gingivitis, poor oral hygiene and high caries activity

**Intervention groups**

In this study, patients with the condition are divided into two groups; in the first group, gingival retraction is performed with cord and in the second group, diode laser retraction is performed.

**Main outcome variables**

The main outcome is marginal adaptation of restoration and the secondary outcome is gingival recession.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20220220054075N1**
Registration date: **2022-03-16, 1400/12/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-16, 1400/12/25**
Update count: **0**

**Registration date**

2022-03-16, 1400/12/25

**Registrant information**

**Name**

sahar raeisi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 83 3729 4660

**Email address**

raissisahar0@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-02-26, 1400/12/07

**Expected recruitment end date**

2022-05-18, 1401/02/28

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluation of the effect of gingival retraction with laser and retraction cord on marginal adaptation and gingival recession in full ceramic crowns for first premolar of maxilla – a clinical trial study

**Public title**
Evaluation of the effect of gingival retraction with laser and retraction cord on gingival recession and marginal adaptation in crowns
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Good general health(The patient has no systemic disease that can affect clinical outcomes) Periodontal health(Plaque index and BOP should be below 20% before prosthetic treatment) There is a good keratinized gum around the abutment tooth (gingival biotype is thick). It should not have obvious signs and symptoms of bruxism or clenching abutment teeth need reconstruction Non-living abutment teeth that have a positive long-term prognosis based on clinical evaluations and radiology Non-living abutment teeth that have a positive long-term prognosis based on clinical evaluations and radiology The teeth have sufficient preparation length to ensure retention and resistance shapes The patient is willing to participate in our study and sign the consent form.
**Exclusion criteria:**
The patient is unwilling or unable to observe adequate oral hygiene (index plate and BOP should be below 20%). abutment teeth have clinical signs. Have loose teeth of second or more degrees. Teeth need periodontal surgery before preparing the crown. Parafunctional habits Periodontitis, severe gingivitis, poor oral hygiene and high caries activity
**Age**
No age limit
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Outcome assessor

**Sample size**
Target sample size: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
A table of random numbers is used for randomization. In Excel software environment, four-digit codes are generated using the RANDBETWEEN command. Each patient is assigned a 4-digit code. If the end digit to the right of the code is 1, 2, 5, 7, 9, the patient is in the yarn group, and if the final digit is 0, 3, 4, 6, 8, the patient is in the group. The laser is placed. All codes are recorded on paper and stored in specific envelopes. The envelopes are arranged randomly and the responsible secretary who is aware of the objectives of the study will give them one of these envelopes before entering the doctor's room when reviewing the criteria for entering the study and recording patient information. The secretary is not aware of the study hypothesis and is not aware of the details of the codes for assigning to groups. The doctor will decide on the treatment process for the patient based on the specified code. Random sequencing is performed by a statistical and epidemiological consultant using Excel software. Registration and evaluation of inclusion criteria is done by the secretary. The secretary has no information about the study hypothesis or the group code. Assignment of intervention is also done by the doctor. The doctor is aware of the group codes. The outcome assessor also has no information about how patients are coded.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
Due to the nature of the intervention, it is not possible to blind patients and only the outcome assessor is unaware of the assignment of individuals to groups. Outcome assessment will be performed by a prosthetist other than the attending physician (evaluator).
**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**
Shahid Beheshti Boulevard - Central Building of Kermanshah Medical Sciences
**City**
kermanshah
**Province**
Kermanshah
**Postal code**
6714869914
**Approval date**
2022-02-22, 1400/12/03
**Ethics committee reference number**
ir.kums.rec.1400.798

## Health conditions studied

**1**

**Description of health condition studied**
Marginal mismatch
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Marginal restoration adaptation
**Timepoint**
before and after veneering
**Method of measurement**
1-parallel Byte Wing Radiography 2- Probe 3- Silicon Replica

## Secondary outcomes

**1**

**Description**
gingival recession
**Timepoint**
before intervention and Two weeks after veneering
**Method of measurement**
Digital caliper

## Intervention groups

**1**

**Description**
Intervention group: After preparation the tooth for molding the gums, we retraction the gingiva with retraction cord.
**Category**
Prevention

**2**

**Description**
Intervention group: After preparation the tooth for molding the gums, we retraction the gingiva with sirona diode laser.
**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Private dental office of Dr sahar raeisi
**Full name of responsible person**
Sahar Raeisi
**Street address**
no.3,floor4,Kosar Building , ayatolah kashani Ave
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kermanshah
**Province**
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**Postal code**
6713737364
**Phone**
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**Email**
raissisahar0@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kermanshah University of Medical Sciences
**Full name of responsible person**
farid najafi
**Street address**
Research Vice Chancellor of Kermanshah University of Medical Sciences ,Central Building, Shahid Beheshti Boulevard, Kermanshah
**City**
kermanshah
**Province**
Kermanshah
**Postal code**
6715847141
**Phone**
+98 83 3729 6591
**Email**
faridnajafi@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**
abolfazl ghodrati golzar

**Position**
under graduated student of dentistry
**Latest degree**
A Level or less
**Other areas of specialty/work**
Dentistry
**Street address**
School of Dentistry ,Shariati St., Kermanshah
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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Kermanshah University of Medical Sciences
**Full name of responsible person**
Sahar Raeisi
**Position**
Assistant Professor
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Specialist
**Other areas of specialty/work**
Dentistry
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No.3 ,4th floor,kosar apartment ayatolah kashani ave
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raissisahar0@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Kermanshah University of Medical Sciences
**Full name of responsible person**
abolfazl ghodrati golzar
**Position**
under graduated student of dentistry
**Latest degree**
A Level or less
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**Email**
agh00108@gmail.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