Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 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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6713737364
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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
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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
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Position
Assistant Professor
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Specialist
Other areas of specialty/work
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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
Other areas of specialty/work
Dentistry
Street address
School of Dentistry ,Shariati St., Kermanshah
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6713954658
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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