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 into3 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 and14 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 Siences

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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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Vice Chancellor for Research and Technology, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd
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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

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Position

Associate professor of Prosthodontics department

Latest degree

Specialist

Other areas of specialty/work

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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