

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of effect of diode laser, astringent paste, and subgingival cord on gingival retraction during impression using a 3D intraoral scanner: a randomized clinical trial

Protocol summary

Study aim

To compare the effect of diode laser, astringent paste, and subgingival cord on gingival retraction during impression using a 3D intraoral scanner

Design

This is a randomized clinical trial, phase II, in which 45 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients need dental veneers referring to the School of Dentistry in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Tooth decay, The need for dental veneers, Exclusion criteria: Inadequate oral hygiene, Periodontal disease

Intervention groups

Intervention group 1: Preparing and cutting teeth and applying temporary resin crown with hidden edges using a 980 nm diode laser with a tip of half a millimeter with a low power of 0.7 to 2 W Intervention Group 2: Preparing and cutting teeth and applying temporary resin crown with hidden edges using gum threads inside the gingival groove Intervention Group 3: Preparing and cutting teeth and applying temporary resin crown with hidden edges using an astringent paste to cover the gingival groove

Main outcome variables

Primary outcome: Gingival retraction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N359**

Registration date: **2020-06-08, 1399/03/19**

Registration timing: **retrospective**

Last update: **2020-06-08, 1399/03/19**

Update count: **0**

Registration date

2020-06-08, 1399/03/19

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of diode laser, astringent paste, and subgingival cord on gingival retraction during impression

using a 3D intraoral scanner: a randomized clinical trial

Public title

Comparison of effect of diode laser, astringent paste, and subgingival cord on gingival retraction during impression using a 3D intraoral scanner

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years, Tooth decay, The need for dental veneers,

Exclusion criteria:

Inadequate oral hygiene, Periodontal disease

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention 1" on one sheet and "intervention 2" on the second sheet and "intervention 3" on the third one. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.UMSHA.REC.1398.719

Health conditions studied

1

Description of health condition studied

Dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Gingival retraction

Timepoint

Before the intervention and immediately after that

Method of measurement

Using a 3D intraoral scanner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Preparing and cutting teeth and applying temporary resin crown with hidden edges using a 980 nm diode laser with a tip of half a mm with low power of 0.7 to 2 W

Category

Treatment - Other

2

Description

Intervention Group 2: Preparing and cutting teeth and applying temporary resin crown with hidden edges using gum threads inside the gingival groove

Category

Treatment - Other

3

Description

Intervention Group 3: Preparing and cutting teeth and applying temporary resin crown with hidden edges using an astringent paste to cover the gingival groove

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry in Hamadan city

Full name of responsible person

Seyed Farzad Kohnepoushi

Street address

School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

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6517838695

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+98 81 3838 0572

Email

m_kohnepoushi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Seyed Farzad Kohnepoushi

Position

Dentistry Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Fariborz Vafaei

Position

Dental Prosthesis Specialist

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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