

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the Effectiveness of Combined Diode Laser and GLUMA Bonding Therapy with Combined Diode Laser and 5% Sodium Fluoride Varnish in Patients with Increased Dentin Sensitivity

Protocol summary

Study aim

Comparison of the effectiveness of combined Diode Laser and GLUMA bonding therapy with combined Diode laser and 5% sodium fluoride varnish in patients with increased dentin sensitivity referred to Laser dept., faculty of dentistry, Shahid Beheshti university of medical sciences, Tehran, Iran. 2019

Design

Clinical trial with control group - with parallel groups and single blind on 60 teeth

Settings and conduct

bonding group: a drop of GLUMA Desensitizer solution is applied on the buccal and lingual for 30 seconds .laser-bonding group: bonding was used according to the mentioned method, then the affected tooth was irradiated directly from the buccal lingual side with a wavelength of 660 nm and a power of 15 mW for 30 seconds, using caps D and E of KONFTEC diode laser, Klas-DX.varnish-laser group: 5% sodium fluoride solution was covered on the buccal and lingual surface by microwave, then the laser is irradiated with the mentioned method. Dental sensitivity was measured by VAS scale immediately after treatment and then 2, 7 and 30 days after treatment.

Participants/Inclusion and exclusion criteria

General health, having ≥ 3 teeth with hypersensitivity to contact stimuli or air blast and consent to 1-month follow-up / Exclusion criteria: having benign or malignant oral disease, long-term use of drugs, having decay in the affected tooth

Intervention groups

Three intervention groups including: bonding, laser-bonding, laser-varnish One insensitive tooth in each patient as a control group

Main outcome variables

intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201219049759N1**

Registration date: **2021-01-28, 1399/11/09**

Registration timing: **retrospective**

Last update: **2021-01-28, 1399/11/09**

Update count: **0**

Registration date

2021-01-28, 1399/11/09

Registrant information

Name

Fahimeh Anbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 2589

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2019-04-19, 1398/01/30

Trial completion date

2019-12-22, 1398/10/01

Scientific title

Comparison of the Effectiveness of Combined Diode Laser and GLUMA Bonding Therapy with Combined Diode Laser and 5% Sodium Fluoride Varnish in Patients with Increased Dentin Sensitivity

Public title

Comparison of the Effectiveness of Combined Diode Laser and GLUMA Bonding Therapy with Combined Diode Laser and 5% Sodium Fluoride Varnish in Patients with Increased Dentin Sensitivity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

good general health Having at least 3 teeth with hypersensitivity to contact stimulus or air blast Agree to follow up for 1 month

Exclusion criteria:

Having benign or malignant oral disease long-term use of the drug having caries in the affected or adjacent tooth enamel cracking congenital defects in the enamel or dentin tooth restoration orthodontic procedures periodontal disease history of vital bleaching history of Periodontal surgery or treatment of hypersensitivity during the last 6 months history of non-surgical treatment of periodontal disease during the past 3 months use of mouthwash containing allergens pregnancy or lactation use of antidepressants and analgesics history of allergies to components Various treatment therapies bruxism abrasion

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

More than 1 sample in each individual

Number of samples in each individual: **3**

Sample size At least 15 samples in each study group, a total of 45 samples (teeth with dentinal hypersensitivity) were determined so that there are at least 3 affected teeth in each participant.

Actual sample size reached: **60**

More than 1 sample in each individual

Actual sample size in each individual: **3**

Considering the possibility of non-cooperation of patients for 1-month follow-up, 60 samples were considered to start the study. All 60 samples participated in follow-up sessions until the end of the study.

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by roll a dice method. This method is used for multi-group studies. Numbers 1 and 2 were considered for the first group, numbers 3 and 4 were considered for the second group, and numbers 5 and 6

were considered for the third group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients did not know how to treat each of the teeth included in the study, and laser eye goggles were used for all patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Chamran Highway, Velenjak St, Tehran, Iran

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Postal code

1983969411

Approval date

2018-10-14, 1397/07/22

Ethics committee reference number

IR.SBMU.DRC.REC.1397.034

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

Increased dentin sensitivity

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

diode laser

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

GLUMA bonding

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

4

Description of health condition studied

5% Sodium Fluoride Varnish

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity on the VAS scale

Timepoint

Before the intervention, immediately after the intervention and at intervals of 2, 7 days and 1 month after the intervention

Method of measurement

VAS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 (bonding): For this purpose, we use the solution of Kulzer GmbH, Germany GLUMA Desensitizer, which in a 5 ml bottle contains 5% glutaraldehyde, 35% HEMA-G and distilled water. One drop of the solution with a applicator is placed on the desired tooth for 30 seconds. It is then dried with a stream of air until the liquid layer on the tooth disappears and its surface loses its luster.

Category

Treatment - Other

2

Description

Intervention group (laser): For this purpose, a KONFTEC Corporation Taiwan KONFTEC Klas-DX diode laser device is used. The laser is applied to the surface of the affected tooth for 30 seconds from the buccal side and 30 seconds from the lingual side with a wavelength of 660 nm and a power of 15 mW using caps D and E, depending on the size of the tooth. The densities in these two caps are 1.8 and 6.9 J / cm² respectively.

Category

Treatment - Other

3

Description

Intervention group (varnish): On the buccal and lingual surface of the target tooth is covered with a microbrush of 5% sodium fluoride solution (Asia Fluoride Chemical Chemistry, Iran). The patient will then be instructed to abstain from eating and drinking for up to one hour after the intervention and to brush for up to 12 hours.

Category

Treatment - Other

4

Description

Control group: In each patient, an insensitive tooth is randomly considered as a control.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Laser section and Clinics of the School of Dentistry of Shahid Beheshti University of Tehran

Full name of responsible person

Fahimeh Anbari

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Shahid Beheshti Dental School, Daneshjoo Blvd., Shahid Chamran Highway, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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Shahid Arabi Street next to Ayatollah Taleghani Hospital, Shahid Chamran Highway Yemen Street, Tehran

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fahimeh Anbari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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