

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of Effect of Fluoride Varnish, Gluma and Er: Cr: YSGG Laser on dentin hypersensitivity in patients with sensitive teeth: a randomized clinical trial.

Protocol summary

Study aim

Determine the 6-month effect of Er: Cr: YSGG laser and several dentinal sensitizers in the treatment of dentinal hypersensitivity

Design

Clinical trials, with parallel, double blind, randomized groups. 175 dentin hypersensitivity teeth will be divided into 5 groups based on the treatment protocol and the results will be compared.

Settings and conduct

Location: Hamadan University of Medical Sciences
Method: First, the participants will be assigned to the groups according to their initial sensitivity. After randomization, the teeth will randomly be divided into five groups based on the received treatment. Patients will be followed after 1 week, 1 month and 6 months after treatment. At each appointment, the evaluation process will be repeated for each patient and the patient's VAS score will be recorded. Finally, the scores obtained from the patients in each group will be statistically analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Good general health; without decay or restoration; without previous treatment; Age and mental ability to determine pain score; No history of bleaching.
Non-inclusion criteria: People with chronic diseases; People who have used toothpaste or desensitizer mouthwash for the past 3 months; People who have had periodontal surgeries in the last 6 months; non vital teeth or vital teeth that have cracks, previous repairs, decay lesions or active periodontal disease; People with deep caries in the vicinity of a sensitive tooth

Intervention groups

Intervention group1: Er: Cr: YSGG laser expose to the sensitive teeth. Intervention group2: varnish fluoride will rub to the sensitive teeth. Intervention group3: first varnish rub on the sensitive teeth, and then laser will be

exposed. Intervention group4: gluma will rub on the sensitive teeth. Intervention group5: first gluma rubbed on the sensitive teeth, and then laser will be exposed.

Main outcome variables

tooth sensitivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190422043343N1**

Registration date: **2019-07-19, 1398/04/28**

Registration timing: **retrospective**

Last update: **2019-07-19, 1398/04/28**

Update count: **0**

Registration date

2019-07-19, 1398/04/28

Registrant information

Name

Mahsa Forouzande

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 81 3838 6410

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-04, 1398/02/14

Expected recruitment end date

2019-06-19, 1398/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effect of Fluoride Varnish, Gluma and Er:Cr: YSGG Laser on dentin hypersensitivity in patients with sensitive teeth: a randomized clinical trial.

Public title

The Effect of Different Desensitiser Protocols on Dentin Hypersensitivity Treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Good general health without any known allergies to commercial dental products The teeth do not have any decay or restoration The patient has not previously received any treatment for dentin hypersensitivity The patient has the ability to determine the pain score in the VAS in terms of age and mentality Patients do not have a history of receiving bleaching treatments

Exclusion criteria:

People with chronic disease with daily episodes of pain that use analgesics, antihistamines, anti-inflammatory drugs, or analgesics during the last 72 hours People who have used toothpaste or antisensitivity mouthwash for the last 3 months. People who have had periodontal surgeries in the last 6 months. non vital teeth or vital teeth with crack, previous restoration, decay lesions, or active periodontal disease. patients without active periodontal disease will remain active in the study People with deep carries adjacent to a sensitive tooth that have a chance of confusing pain with sensitive tooth pain

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **35**

More than 1 sample in each individual

Number of samples in each individual: **5**

The teeth with dentin hypersensitivity that can vary from one tooth to all teeth and in the above box, an average of 5 teeth were mentioned

Randomization (investigator's opinion)

Randomized

Randomization description

At first, participants are classified according to their

initial sensitivity and then randomly divided into random classes in a randomized block to ensure that each group is in the same state of origin in terms of initial sensitivity. Block size and randomization method will be determined by another person Other than the therapists and evaluators. Given the fact that the stimulus air flow is effective in evaluating the effectiveness of the therapeutic methods compared to the adjacent teeth, only one treatment will be used in each jaw quadrant.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind study. One operator irradiate laser and apply desensitiser, while the other operator will assess the sensitivity. Also, patients will not be aware of the treatment they will receive and on the teeth Patients whose therapeutic protocol does not include lasers will be targeted by the aiming beam.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name****Secondary trial Id****Registration date**

empty

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

Hamadan University of Medical Sciences

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Shahid Fahmideh

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6516647447

Approval date

2019-05-05, 1398/02/15

Ethics committee reference number

IR.UMSHA.REC.1398.095

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

Dentin hypersensitivity

ICD-10 code

K03.8

ICD-10 code description

Other specified diseases of hard tissues of teeth

Primary outcomes

1

Description

Tooth sensitivity amount

Timepoint

After 1 week, 1 month and 6 months

Method of measurement

VAS score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:laser: Laser Er, Cr: YSGG (Waterlase, Biolase Technology, Irvine, CA) perpendicular to the dentin surface by moving scanning movements at a distance of 1 mm with zero percent of air and water for 30 seconds with a frequency of 20 Hz and a power of 0.25 W (44.3J / cm²) whit M Z6 sapphire tip with a diameter of 600 micron and a length of 6 mm will be exposed on the sensitive teeth.

Category

Treatment - Devices

2

Description

Intervention group 2 (fluoride varnish):A cotton roll for isolating the environment and preventing the varnish mix with saliva will be used. Then, a thin layer of Fluoride varnish (Ivoclar Vivadent), will be applied on the surface of the tooth with a disposable microbrush in accordance with the factory's instructions. Two to three layers of varnish will be applied to the surface of the teeth on the same day. Patients will be told to stop taking any food or carbonate drink for an hour after using varnish.

Category

Treatment - Drugs

3

Description

Intervention group 3 (fluoride varnish and laser): The varnish will be used similarly to the method used in group 2 on the teeth surface, and the varnish will remain in place for 60 seconds, and then the laser will be exposed with the same radiant profile of the group 1 on its surface.

Category

Treatment - Drugs

4

Description

Intervention group 4 (Gluma): A cotton roll for rubbing the Gluma (Heraeus Kulzer GmbH, Hanau, Germany) will be used with a gentle but firm motion on the tooth surface. After 30 to 60 seconds, the dentin will dry completely until The fluid will disappear and the surface will lose its gloss state.

Category

Treatment - Drugs

5

Description

Intervention group 5 (Gluma and laser): The Gluma will be used similar to that used in group 4 on the teeth surface. then, the laser will be exposed with the same radiant profile of the group 1 on its surface.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

Mahsa Forouzande

Position

dentistry resident

Latest degree

Medical doctor

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