

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative evaluation of the effect of Gluma Desensitizer and high power Diode Laser 980-nm and combination use of them on reduction of dentin hypersensitivity

Protocol summary

Study aim

Comparative evaluation of the effect of Gluma Desensitizer and Diode Laser 980-nm and combination use of them on reduction of dentin hypersensitivity

Design

Randomized clinical trial with control group, with parallel groups, single blinded

Settings and conduct

This study will be done on patients with dentin hypersensitivity referring to department of periodontics of Isfahan dental school. Effect of Gluma desensitizer and high power diode laser 980 nm and combination use of them will be evaluated. Statistical analyzer is blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients referring to department of periodontics of Isfahan Dental School who have 3 teeth with complaint of cervical dentin sensitivity that are not adjacent to each other. Patients should be available for three months during the study period and sign the informed consent form. The teeth do not need restorative treatment, people over 18 years old. Exclusion criteria: existence of caries, crack and pulpitis, cervically restored teeth, coronary fractures. Pregnant and lactating people, smoking patients, patients who have used anti-sensitive toothpaste or other medicines for the past 6 months, bleaching in past 6 months, unsuitable diet (use of sour and acidic foods), People who have high O'Leary index in follow up sessions (higher than 25%).

Intervention groups

1- Intervention group1: treatment with gluma desensitizer from Kulzer Company. 2- intervention group 2: treatment with high power diode laser (980 nm, 1 watt), with a distance of 1mm from the tooth and duration of 30 seconds 3- intervention group 3: treatment with combination of gluma desensitizer and high power diode laser 980 nm 4- control group:

treatment without gluma desensitizer and laser, just applying conductor light of laser (off laser set) and scaling

Main outcome variables

Dentin sensitivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120901010703N5**

Registration date: **2022-02-24, 1400/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-24, 1400/12/05**

Update count: **0**

Registration date

2022-02-24, 1400/12/05

Registrant information

Name

Narges Naghsh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 5564

Email address

n_naghsh@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative evaluation of the effect of Gluma Desensitizer and high power Diode Laser 980-nm and combination use of them on reduction of dentin hypersensitivity

Public title
Comparative evaluation of the effect of Gluma Desensitizer and high power 980-nm Diode Laser and combination of them on reduction of dentin hypersensitivity

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to the general and specialized periodontics department of Isfahan Dental School have 3 teeth with complaints of cervical dentin sensitivity and sensitivity to cold stimuli that are not adjacent to each other. Patients should be available for three months during the study period and sign the informed consent form .Teeth do not need restorative treatment People over 18 years old
Exclusion criteria:
Caries, crack and pulpitis, Existence of active caries, cervically restored teeth, coronary fractures .Pregnant and lactating people smoking Patients and who have used anti-sensitive toothpaste and other medicines for the past 6 months. bleaching in past 6 months, diet (use of sour and acidic foods), People who have high O'leary index in follow up sessions (higher than 25%)

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **3**
3 nonadjacent hypersensitive teeth

Randomization (investigator's opinion)
Randomized

Randomization description
According to the number of available groups (4 groups for intervention and control), there are papers with the group name written on them and placed in a box. Each sample person picks a paper from the box and receives the desired treatment.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyzer and patient do not know the type of received treatment

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Vice Chancellor for Research and Technology;
Building No. 4; Isfahan University of Medical Sciences and Health Services; Hezar Jerib St.,
City
isfahan
Province
Isfahan
Postal code
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Approval date
2021-12-13, 1400/09/22

Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.384

Health conditions studied

1

Description of health condition studied
Dentin hypersensitivity

ICD-10 code
K03.89

ICD-10 code description
Other specified diseases of hard tissues of teeth

Primary outcomes

1

Description
Amount of patient's pain (dentin hypersensitivity)

Timepoint
Before treatment, 15 minutes after treatment in the first session, one week after the first session, two weeks after the first session, one month after the first session, tree months after the first session

Method of measurement
Use of cold spray, use of air syringe of unit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intervention group 1 treatment with gluma desensitizer from Kulzer Company. gluma desensitizer apply on dry teeth 60 seconds and dry for 5 seconds.

Category

Treatment - Drugs

2

Description

Intervention group: intervention group 2 treatment with laser diode 980 nm (1 watt, 980 nm) distance from tooth 1mm duration 30 seconds

Category

Treatment - Devices

3

Description

Intervention group: intervention group 3 treatment with combination of gluma desensitizer and followed by laser diode 980 nm . gluma desensitizer apply on dry tooth 60 seconds and dried for 5 seconds then diode laser (1 watt ,980nm) apply on tooth with distance 1mm for 30 seconds.

Category

Treatment - Devices

4

Description

Control group: control group treatment without gluma desensitizer and apply only conductor light of laser (off laser set) and with SRP on patients

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontics, School of Dentistry,
Isfahan University of Medical Sciences

Full name of responsible person

Azin Bazmara

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Department of Periodontics; Dentistry School; Isfahan
University of Medical Sciences and Health Services;
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash

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Technology; Isfahan University of Medical Sciences
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siavash@med.mui.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Narges Naghsh

Position

Associate 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