

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Evaluation the effect of nano bioglass and diode laser (980 nm) in dentin hypersensitivity treatment: a 6-month clinical trial

#### Protocol summary

##### Study aim

In this study the effect of nanobiogloss with the help of diode laser will be investigated to determine whether the therapeutic protocol with the help of this laser can have the greatest effect on reducing sensitivity.

##### Design

A randomized controlled clinical trial with parallel groups non-blind randomization on 15 patients was used for randomization of Excel software.

##### Settings and conduct

The test is done in Hamedan Dental School of Medical Sciences in the laser department. The degree of sensitivity of teeth to evaporative stimuli before and after treatment will be quantified by airflow at 35 psi. The tooth was dried and isolated, and a cold air flow was injected into the tooth from a distance of one centimeter for 1 second and the tooth response to this stimulus was recorded through the visual analog scale (VAS).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria are: No known allergy to commercial dental products/There is no residue or residue/No treatment received/No history of receiving teeth whitening treatments.

##### Intervention groups

Control group: No laser or nanobio-glass applied on dentin surfaces of teeth. NB group: the solution was applied to the dentin surfaces of the teeth using an applicator brush for 20 seconds in two steps. Group L (laser): Diode laser with special radiation characteristics, scanning in occlusal and mesiodistal directions dentin surfaces of teeth. nBL group: The surfaces of the teeth were first prepared similar to the nB group, and then they were treated with lasers similar to group L. LnB group: Diode lasers were applied on the surfaces of teeth similar to group L and then similar to nB group. Nanobiogloss was applied.

##### Main outcome variables

Decreased dental sensitivity after treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240109060667N1**

Registration date: **2024-02-05, 1402/11/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-02-05, 1402/11/16**

Update count: **0**

##### Registration date

2024-02-05, 1402/11/16

##### Registrant information

##### Name

zahra khalafi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 917 758 5429

##### Email address

sahel21975@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-10, 1402/10/20

##### Expected recruitment end date

2024-07-10, 1403/04/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of nano bioglass and diode laser (980 nm) in dentin hypersensitivity treatment: a 6-month clinical trial

#### Public title

Evaluation the effect of nanobioglass and diode laser (980 nm) in dentin hypersensitivity treatment

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Good general health No known allergy to commercial dental products Teeth studied have no decay or repair The patient has not previously received treatment for their dentinal allergy. The patient should be able to determine the pain score in VAS in terms of age and mentality. Patients should not have a history of receiving bleaching treatments by bleaching method.

##### Exclusion criteria:

People with chronic diseases with episodes of daily pain who have taken anticonvulsants, analgesics , antihistamines , sedatives , anti-inflammatory or analgesic drugs in the past 72 hours. People who have used toothpaste or hypoallergenic mouthwashes in the past 3 months. People who have had periodontal surgery in the past 6 months. White bread teeth or white teeth that have cracks, previous repairs, caries lesions or active periodontal disease. Subjects with periodontal recession will remain active in the study. People with deep cavities in the vicinity of sensitive teeth are likely to be mistaken for sensitive tooth pain.

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **10**

The number of sensitive teeth in each person is at least 5-10

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### 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 Hamedan University of Medical Sciences

##### Street address

Hamedan University of Medical Sciences, Shahid Fahmideh Blvd., Pajoohesh Sq., Hamedan, Iran

##### City

Hamedan

##### Province

Hamadan

##### Postal code

۶۵۱۷۸۳۸۷۳۶

#### Approval date

2023-11-25, 1402/09/04

#### Ethics committee reference number

IR.UMSHA.REC.1402.555

## 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

People whose VAS scores are above 5.

#### Timepoint

Patients were called for followup after 1 week, 1 month and 6 months after treatment. At each visit, the mentioned evaluation process was repeated for each patient and VAS score was recorded.

#### Method of measurement

The lowest score is zero which means the situation is completely painless, and the highest score is 10, which means the maximum amount of pain that a person can experience.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: No laser or nanobio-glass were applied on dentin surfaces.

#### Category

N/A

## 2

### Description

NB group (Nanobioglus): 50% solution of biogas nanoparticles and distilled water was prepared. Then, the ultrasonic probe with 20 kHz characteristics was homogenized for 20 seconds and 20 cycles of solution. Then, the solution was applied to dentin surfaces of teeth using an applicator brush for 20 seconds in two steps.

### Category

Treatment - Drugs

## 3

### Description

Intervention group: Group L (laser): Diode laser with special radiation characteristics (wavelength 980 nm, power 3 watts, SSP mode, 5 mm non-contact), scanning in occlusal and mesiodistal directions and vice versa with total radiation time of 21 min/cm<sup>2</sup> on dentin surfaces of teeth.

### Category

Treatment - Other

## 4

### Description

Intervention group: Intervention group: nBL group (Nanobioglus + laser): The surfaces of the teeth were first prepared similar to the nB group and then they were applied to the same laser as group L.

### Category

Treatment - Other

## 5

### Description

Intervention group: Intervention group: LnB group (laser+nanobioglus): Diode lasers were applied on the surfaces of teeth similar to group L and then similar to nB group Nanobioglus was applied.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hamadan Dental School Restorative Department

##### Full name of responsible person

Zahra Khalafi

##### Street address

Shahid Fahmideh Blvd., Pajouhesh Sq., Hamedan, Iran

##### City

Hamedan

##### Province

Hamadan

##### Postal code

۶۵۱۷۸۳۸۷۳۶

### Phone

+98 81 3131 0000

### Email

webda@umsha.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr Reza Shokoohi

##### Street address

Shahid Fahmideh Blvd., Pajouhesh Sq., Hamedan, Iran

##### City

Hamedan

##### Province

Hamadan

##### Postal code

۶۵۱۷۸۳۸۷۳۶

##### Phone

+98 81 3131 0000

##### Email

webda@umsha.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Hamadan 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

Zahra Khalafi

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dentistry

#### Street address

Shahid Fahmideh Blvd., Pajouhesh Sq., Hamedan, Iran

#### City

Hamadan

**Province**

Hamadan

**Postal code**

۶۵۱۷۸۳۸۷۳۶

**Phone**

+98 917 758 5429

**Fax****Email**

sahel21975@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Zahra Khalafi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Shahid Fahmideh Blvd., Pajouhesh Sq., Hamedan, Iran

**City**

Hamadan

**Province**

Hamadan

**Postal code**

۶۵۱۷۸۳۸۷۳۶

**Phone**

+98 917 758 5429

**Fax****Email**

sahel21975@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Zahra Khalafi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Shahid Fahmideh Blvd., Pajouhesh Sq., Hamedan, Iran

**City**

Hamadan

**Province**

Hamadan

**Postal code**

۶۵۱۷۸۳۸۷۳۶

**Phone**

+98 917 758 5429

**Fax****Email**

sahel21975@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

I don't have any more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available