

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### comparing the effectiveness of sodium fluoride varnish, diode laser and potassium nitrate in reducing post-office bleaching hypersensitivity

#### Protocol summary

##### Study aim

Choosing the proper substance to reduce sensitivity after office bleaching

##### Design

After accepting the patients applying for Inclusion and exclusion criteria and explaining the objectives of the study and the implementation method, the patients enter the research. After checking the level of sensitivity with the help of Visual Analog Scale (VAS) and obtaining informed consent, bleaching treatment is started, and all patients undergo office bleaching treatment using 35% hydrogen peroxide (Whiteness HP, FGM). Immediately after bleaching, tooth sensitivity is evaluated with the help of the VAS. First, people are randomly subjected to one of the treatment methods. The level of dental sensitivity immediately after each treatment and also 24 and 48 hours after the treatment should be measured by the trained VAS method and informed by phone and recorded in the questionnaire.

##### Settings and conduct

Restorative department of Yazd Faculty of Dentistry

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1, at least 18 years old 2- have eight caries free maxillary anterior teeth without restorations on the labial surfaces and 3, shade A2 or darker based on Vita 4, Patients who had not undergone tooth whitening procedures 5, non previous tooth sensitivity 6, non pregnant/lactating, 7, non severe internal tooth discoloration 8, non bruxism habits, 9, non severe gingival recession 10, non class 5 caries 11, non-exposed dentin or any condition that changes tooth sensitivity exclusion criteria: 1, Non-cooperation in reporting sensitivity level 2- Non-cooperation in treatment

##### Intervention groups

1: potassium nitrate 2: 5% sodium fluoride varnish 3: Low power diode laser treatment

##### Main outcome variables

Sensitivity level (immediately, 24, 48 hour) after anti-sensitivity treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230729058962N1**

Registration date: **2023-08-08, 1402/05/17**

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

Last update: **2023-08-08, 1402/05/17**

Update count: **0**

##### Registration date

2023-08-08, 1402/05/17

##### Registrant information

##### Name

Farnaz Farahat

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3625 5883

##### Email address

f.farahat@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-06, 1402/05/15

##### Expected recruitment end date

2024-02-04, 1402/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparing the effectiveness of sodium fluoride varnish, diode laser and potassium nitrate in reducing post-office bleaching hypersensitivity

**Public title**

reducing post-office bleaching hypersensitivity

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

1- at least 18 years old 2-Participants were required to have eight caries-free maxillary anterior teeth without restorations on the labial surfaces and 3- shade A2 or darker based on vita 4- Patients who had not undergone tooth-whitening procedures 5- previous tooth sensitivity 6-not pregnant/lactating, 7- not severe internal tooth discoloration (tetracycline stains, fluorosis, pulpless teeth), 8- not bruxism habits, 9- not severe gingival recession 10- not class 5 caries 11- not exposed dentin or any condition that changes tooth sensitivity

**Exclusion criteria:****Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

people are randomly divided into three groups, 1, 2, and 3, then a number is selected from numbers 1 to 3 using the random number table and attributed to the first method of reducing sensitivity (potassium nitrate) and the second random number is attributed to the second method (sodium fluoride varnish). And the third random number is attributed to the third method (laser). Each group is subjected to one of the following treatment methods: Method 1: Treatment with potassium nitrate Method 2: treatment with 5% sodium fluoride varnish Method 3: Low power diode laser treatment

**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**

Research Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd - Faculty of Dentistry

**Street address**

Shahid Bahonar square

**City**

yazd

**Province**

Yazd

**Postal code**

8916978477

**Approval date**

2023-05-29, 1402/03/08

**Ethics committee reference number**

IR.SSU.DENT.REC.1402.022

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

tooth sensitivity

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Sensitivity level after bleaching based on VAS

**Timepoint**

before, immediately, 24 hours after, 48 hours after OB

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group: Treatment with potassium nitrate

**Category**

Treatment - Drugs

**2****Description**

Intervention group: treatment with 5% sodium fluoride varnish

**Category**

Treatment - Drugs

3

**Description**

Intervention group: Low power diode laser treatment

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Shahid Sadoughi Dentistry School of Yazd

**Full name of responsible person**

Zahra Zare bidoki

**Street address**

Emam Ave, Emam Reza Blvd

**City**

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**Province**

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**Postal code**

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**Phone**

+98 35 3625 5881

**Email**

z.zarebidaki76@gmail.com

**Web page address**

<https://web.ssu.ac.ir/fa/202>

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Amin Salehi Abarghoie

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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**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Zahra Zare bidoki

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries**

**Contact**

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Yazd University of Medical Sciences

**Full name of responsible person**

Zahra Zare bidoki

**Position**

resident

**Latest degree**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

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**Latest degree**

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**Other areas of specialty/work**

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z.zarebidaki76@gmail.com

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Information about the level of dental sensitivity of people is shared in different groups

**When the data will become available and for how long**

Access starts 6 months after the publication of the article

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

No publication of results is allowed

**From where data/document is obtainable**

1- Email to z.zarebidaki76@gmail.com 2- Call 09134509675 3- Call 03538213280 4- Correspondence with postal code 8916135115 Zahra Zare Bidaki

**What processes are involved for a request to access data/document**

Sending a request through one of the communication channels and fully explaining the purpose of the request and how to use the information

**Comments**