Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

comparing the effectiveness of sodium floride varnish, diod laser and potassium nitrate in reducing post-office bleaching hypersensivity

Protocol summary

Study aim
Choosing the proper substance to reduce sensitivity after office bleaching

Design
After accepting the patients applying for Inclusion and exciusion 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,shadeA2 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 sever gindival recesion 10, non class5 caries 11, non- expose dentin or any condition that changes tooth sensivity 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-sensivity 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 floride varnish, diod laser and potassium nitrate in reducing post-office bleaching hypersensivity

Public title
reducing post-office bleaching hypersensivity
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- shadeA2 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 sever gindival recesion 10- not class5 caries 11- not expose dentin or any condition that changes tooth sensivity
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 Denti
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 sensivity
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sensitivity level after bleaching besed on VAS
Timepoint
before, immidiatly.24hour after.48 hour 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
yazd
Province
Yazd
Postal code
۸۹۱۴۸۱۵۶۶۷
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
Street address
Emam Ave, Emam Reza Blvd
City
yazd
Province
Yazd
Postal code
۸۹۱۴۸۱۵۶۶۷
Phone
+98 35 3625 5881
Email
z.zarebidaki76@gmail.com
Web page address
https://web.ssu.ac.ir/fa/202
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
Street address
Felestin Blvd
City
yazd
Province
Yazd
Postal code
8916135115
Phone
+98 35 3821 3280
Email
z.zarebidaki76@gmail.com

Person responsible for scientific 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
Street address
Felestin Blvd
City
yazd
Province
Yazd
Postal code
8916135115
Phone
+98 35 3821 3280
Email

z.zarebidaki76@gmail.com

Person responsible for updating data

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

Street address
Felestin Blvd

City
yazd

Province
Yazd

Postal code
8916135115

Phone
+98 35 3821 3280

Email
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