Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Effect of toothpaste containing nanohydroxyapatite particles on dental sensitivity , color change and Gingival Index during home bleaching treatment

Protocol summary

Study aim

Comparison of dental sensitivity intensity, rate of tooth discoloration and gingival index during home bleaching treatment following the use of toothpastes containing nanoparticles of apatite and common toothpaste

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 40 patients. The random allocation rule method (blocking with balls) was used to randomize.

Settings and conduct

This study was performed on 40 patients in the field of bleaching treatment and in the rehabilitation department of Zahedan Dental School. The type of toothpaste will be unclear to the participant and the student (outcome assessor) by simulating their external coverage by the tutor.

Participants/Inclusion and exclusion criteria

Inclusion criteria:having natural front teeth with A2, B2, C2, D2 and darker colors (Vitapan Classic Shade); at least 24 teeth; no front restoration; good oral hygiene; patient satisfaction, people without decay; Gingivitis and periodontal disease; people with dental root exposure; no NCCL (Non-Caries Cervical Lesions); no orthopedic treatment; Anti-allergy compounds over the past three months; lack of pregnancy and lactation; lack of calculus; no history of bleaching treatment in the past; non-smokers; no change The colors of fluorosis and Tetracycline Exit criteria:Lack of willingness of the participant to continue treatment ,Severe allergy due to bleaching treatment

Intervention groups

1- Case (toothpaste consumers containing nanohydroxy apatite particles) 2- Control (common toothpaste consumers)

Main outcome variables

Intensity of dental sensitivity - rate of discoloration - gingival index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200509047374N1**
Registration date: **2020-05-17, 1399/02/28**
Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**
Update count: **0**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name

Faezeh Elahi Chatrodi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of Effect of toothpaste containing nanohydroxyapatite particles on dental sensitivity , color change and Gingival Index during home bleaching treatment

Public title
Evaluation of the clinical effects of nanohydroxy apatite toothpaste during home bleaching treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having natural front teeth with colors A2, B2, C2, D2 and darker (Vitapan Classic Shade) Have at least 24 teeth Lack of any kind of frontal restoration Proper oral hygiene People without caries in the front teeth Lack of Gingivitis and Periodontal Diseases No dental root exposure Lack of NCCL (Non Caries Cervical Lesions) Lack of ortho treatment Patients without a history of dental sensitivity to cold and heat or expressing allergies with airborne powder tests Do not use any anti-sensitivity compounds for the past three months No pregnancy or lactation Lack of Calculus People without a history of bleaching treatment in the past No smoking People without florosis and tetracycline
Exclusion criteria:
Lack of willingness of the participant to continue treatment Severe sensitivity due to bleaching treatment
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Random Allocation Rule Method (In this method, a block of 40 people is considered for sample size and 40 balls with numbers 1 to 40 are placed in one container and the first 20 balls are randomly removed and their sequence is recorded. And are placed in the first group and the remaining 20 items are placed in the second group, so that the balance in the number of people allocated in the groups will be obtained at the end of the study) will be placed in one of the two study groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to simulate toothpaste, due to the similarity of the outer coating of the tube, the outer coating of the toothpaste is removed and the same coatings are placed and coded (by the instructor). Toothpaste will be unspecified for participants and students(Consequence Assessor).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences
Street address
Iran, Zahedan, Dr. Hesabi Square, Zahedan University of Medical Sciences
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Province
Sistan-va-Balouchestan
Postal code
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Approval date
2020-04-26, 1399/02/07
Ethics committee reference number
IR.ZAUMS.REC.1399.032

Health conditions studied

1

Description of health condition studied
Tooth sensitivity after bleaching
ICD-10 code
Z40,Z54
ICD-10 code description
Persons encountering health services for specific procedures and health care

Primary outcomes

1

Description
The severity of tooth sensitivity
Timepoint
Days 1, 3, 7, 10 and 14 after the start of bleaching
Method of measurement
based on the VAS (Visual Analog Scale)test

2

Description
The rate of tooth discoloration

Timepoint
Days 1, 3, 7, 10 and 14 after the start of bleaching
Method of measurement
Chromaticity (color intensity) with Easy shade device

3

Description
Gingival index
Timepoint
Days 1, 3, 7, 10 and 14 after the start of bleaching
Method of measurement
During a clinical examination with a probe and observing the condition of the gums

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Do prophylaxis with oil-free prophylactic paste, to remove foreign pigments one week before bleaching treatment, teaching how to brush and floss correctly (brush 3 times a day at the right time, noon, night and floss once a night), prepare a template Alginate, made by each vacuum-specific home remover by vacuum device, uses a tri-containing carbamide proxide bleaching gel with 16% whiteness perfect (FGM Dental-products, Joinville, Sc, brazil) for 4 hours a day for up to 14 days and uses common toothpaste (Pharmad Total Care Toothpaste 100 mg, Dr. Akhavi Laboratory Company in Tehran, Made in Iran) during the period of use of a tar containing bleaching agents, delivery one anti-sensitivity tube UltraEz(Opalescencc, USA) and a number of codeine acetaminophen tablets (/ 10mg300) for pain relief medications
Category
Treatment - Drugs

2

Description
Intervention group: Do prophylaxis with oil-free prophylactic paste, to remove foreign pigments one week before bleaching treatment, teaching how to brush and floss correctly (brush 3 times a day at the right time, noon, night and floss once a night), prepare a template Alginate, home-made tri-person trials by vacuum machine, use of tri-containing carbamide proxide bleaching gel 16% whiteness perfect (FGM Dental-products, Joinville, Sc, brazil) for 4 hours a day for up to 14 days and use toothpaste containing 15% of Pharmed Normative Apatite Nanoparticles (Pharmad N-HAP Sensitive Toothpaste 100 mg, Dr. Akhavi Laboratory Company in Tehran, Made in Iran) during Use Bleaching of the more ingredients, deliver a ānti-sensitivity tube UltraEz (Opalescencc, USA) and a number acetaminophen codeine (/ 10mg300) in order to relieve the unbearable pain medications
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Restorative , Zahedan School of Dentistry
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Sponsors / Funding sources

1

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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
Zahedan 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
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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
No need to publish
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