

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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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+98 54 3337 2116

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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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Sistan-va-Balouchestan

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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(Opalescenc, 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 Pharmad 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 anti-sensitivity tube UltraEz (Opalescenc, 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

Full name of responsible person

Dr. Somayeh Hosseini Tabatabai

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Faeze Elahi Chatrudi

Position

Dentistry Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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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