

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation of Whitening Effectiveness and Tooth Sensitivity of the Formulated In-Office Bleaching Gel Containing 40% Hydrogen Peroxide and a Remineralizing Agent: A Triple Blinded Randomized Clinical Trial

Protocol summary

Study aim

Determining the Effect of Bleaching Gel Containing a Remineralizing Agent on Whitening and Tooth Sensitivity After Bleaching

Design

A Triple Blinded Randomized Controlled Clinical trial with a parallel group design of 32 patients. Sealed Envelopes Are Used for Randomization.

Settings and conduct

This Study Will be Performed in a "Split Mouth" Design. In the Quadrant of Control a Bleaching Gel Containing 40% Hydrogen Peroxide Is Used, and In the Quadrant of Test a Bleaching Gel with a Remineralizing Agent Is Used. Before Starting, Immediately After Finishing Work, 24 Hours, One Week, One Month, Three Months and Six Months Later, the Tooth Sensitivity to Cold, Touch and Spontaneous Sensitivity are Assessed by "Visual Analogue Scale" and the color of the teeth is Recorded by the Spectrophotometer. The Location of the Study Is Mashhad Dental School. The Study Is Triple Blinded: In this way, the Participants, the Analyzer, and the Statistician Are Unaware of the Allocation of the Test and Control Groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 18 to 40 Years Old; Indication of Bleaching Treatment; Absence of Caries or Restoration on the Labial Surface of the Teeth; Good Oral Hygiene; Absence of Tooth Sensitivity
No Inclusion Criteria: History of Disease or Long-Term Medication; Using Orthodontic Appliances; Periodontal Disease; Lactating and Pregnant Women; Conditions of Increased Dental Sensitivity such as Exposed Dentin; History of Anti-Sensitivity Treatments in the Last Six Months; History of Bleaching Treatment

Intervention groups

Intervention Group: Using Bleaching Gel Containing 40% Hydrogen Peroxide and a Remineralizing Agent
Control Group: Using Bleaching Gel Containing 40% Hydrogen

Peroxide and Free of Remineralizing Agent

Main outcome variables

Tooth Sensitivity to Cold, Touch and Spontaneous sensitivity Amount of Tooth Whitening

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200906048639N1**

Registration date: **2021-02-28, 1399/12/10**

Registration timing: **prospective**

Last update: **2021-02-28, 1399/12/10**

Update count: **0**

Registration date

2021-02-28, 1399/12/10

Registrant information

Name

Mahla Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3865 8162

Email address

rezaeim981@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Whitening Effectiveness and Tooth Sensitivity of the Formulated In-Office Bleaching Gel Containing 40% Hydrogen Peroxide and a Remineralizing Agent: A Triple Blinded Randomized Clinical Trial

Public title
Evaluation of Whitening Effectiveness and Tooth Sensitivity of the Formulated In-Office Bleaching Gel Containing Hydrogen Peroxide and a Remineralizing Agent

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients for whom Bleaching Treatment Is Indicated, So that the Teeth that Need Bleaching Should be Free of Caries or Previous Restoration on the Labial Surface Patients in Optimal General and Oral health Conditions Patients without Complaints of Dental Sensitivity to Touch and to Thermal Stimuli Patients Aged 18 to 40 Years

Exclusion criteria:

Patients with a Long History of Illness or Medication Patients Using Orthodontic Appliances Patients with Periodontal Disease or Poor Oral Hygiene Children and Women who Are Breastfeeding or Pregnant Patients with Conditions of Hypersensitivity such as Dentin Exposure and Non-Carious Cervical Lesions People who Have a History of Anti-Sensitivity Treatments in the Last Six Months People who Have Previously Had Bleaching Treatment

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**
More than 1 sample in each individual
Number of samples in each individual: **2**
This Study Will be Performed in a "Split Mouth" Design. One Quadrant of the Maxilla Arch Is Considered as the Test Group and the Opposite Quadrant Considered as the Control Group.

Randomization (investigator's opinion)
Randomized

Randomization description
In This Study, the "Simple" Randomization Method Is

Used. Sealed Envelopes Are Randomly Given to Each Participant to Determine their Quadrant of Testing and Control. This Is Done by Someone Other than the Evaluator of the Study Parameters.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In This Study, the Participants, the Analyzer, and the Statistician Are Unaware of the Allocation of the Groups (Assigning the Right or Left Maxillary Quadrant to the Test or Control Group). In This Way, Inserting the Bleaching Gels into the Test and Control Syringes as well as the Application of Gels on the Teeth by One Person, the Evaluation of the Color and Sensitivity of the Teeth by Another Person and the Statistical Analysis of Data by Another Person Will be Done.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad Dental School

Street address

School of Dentistry, in front of Mellat Park, First of Vakilabad Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2020-12-22, 1399/10/02

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1399.114

Health conditions studied

1

Description of health condition studied

Tooth Discoloration

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Tooth Sensitivity to Cold Stimulus

Timepoint

Before Starting Treatment, Immediately After Treatment, 24 Hours, One Week, One Month, Three Months and Six Months After Treatment

Method of measurement

Using the "Visual Analogue Scale" from Minimum Sensitivity (Score 0) to Unbearable Pain (Score 10): The Cold Stimulus Is Applied to the Surface of the Lateral Tooth in the Cervical Third of the Tooth by Air Force from a Distance of One Centimeter for Three Seconds.

2

Description

Tooth Sensitivity to Touch with Explorer

Timepoint

Before Starting Treatment, Immediately After Treatment, 24 Hours, One Week, One Month, Three Months and Six Months After Treatment

Method of measurement

Using the "Visual Analogue Scale" from Minimum Sensitivity (Score 0) to Unbearable Pain (Score 10): The Touch Stimulus Is Produced by the Tip of a Explorer on the Cervical of the Tooth.

3

Description

Spontaneous Sensitivity Reported by Patients

Timepoint

Before Starting Treatment, Immediately After Treatment, 24 Hours, One Week, One Month, Three Months and Six Months After Treatment

Method of measurement

Using the "Visual Analogue Scale" from Minimum Sensitivity (Score 0) to Unbearable Pain (Score 10): Spontaneous Sensitivity Will be Recorded by Asking Patients.

4

Description

Bleaching Gel Whitening or Discoloration of the Teeth

Timepoint

Before Starting Treatment, Immediately After Treatment, 24 Hours, One Week, One Month, Three Months and Six Months After Treatment

Method of measurement

Tooth Color is Recorded by Spectrophotometer, then the Amount of Total Discoloration Between Each Measurement Step, Is Calculated by the Formula $\Delta E = \sqrt{[(a2-a1)]^2 + [(b2-b1)]^2 + [(L2-L1)]^2}$ for Each Tooth.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Custom Made Bleaching Gel Containing 40% Hydrogen Peroxide and a Remineralizing Agent Is Placed on the Enamel Surface for 45 Minutes (Three 15-Minutes Periods).

Category

Treatment - Other

2

Description

Control group: The Custom Made Bleaching Gel Containing 40% Hydrogen Peroxide and Free of Remineralizing Agent Is Placed on the Enamel Surface for 45 Minutes (Three 15-Minutes Periods).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dental School

Full name of responsible person

Mahla Rezaei

Street address

School of Dentistry, in front of Mellat Park, First of Vakilabad Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Deputy of Research and Technology, Ghoreshi Building, Near The Hoveyzeh Cinema, University Street

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Province

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9138813944

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Email

vcresraech@mums.ac.ir

Web page address

https://v-research.mums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mahla Rezaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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5th Floor, No. 69, Daneshjoo 17 St., Daneshjoo Blvd.,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamideh Sadat Mohammadipour

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available