

# 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  $\Delta E = \sqrt{[(a_2 - a_1)]^2 + [(b_2 - b_1)]^2 + [(L_2 - L_1)]^2}$  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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#### Province

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#### Postal code

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#### Phone

+98 51 3882 9501

#### Email

contact@email.com

#### Web page address

<https://dentistry.mums.ac.ir/>

## 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, Ghoreishi Building, Near The Hoveyzeh Cinema, University Street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9138813944

#### Phone

+98 51 3841 1538

**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

**Street address**

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**

Dentistry

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## Person responsible for updating data

**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

**Street address**

5th Floor, No. 69, Daneshjoo 17 St., Daneshjoo Blvd.,  
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Razavi Khorasan

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**Email**

rezaeiM981@mums.ac.ir

## 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