

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation and comparison of the effects of bleaching gel containing 1% sodium hexametaphosphate on color stability and dental sensitivity during and after bleaching: a randomized, triangular blinded clinical trial study.

Protocol summary

Study aim

Evaluation of the effect of bleaching gel containing 1% sodium hexametaphosphate on color stability and dental sensitivity during and after bleaching.

Design

Randomized, randomized, triple blind clinical trial

Settings and conduct

After obtaining informed consent from the applicants participating in the study, and after cleaning the teeth with pumice powder, the primary color of the anterior teeth is evaluated by a spectrophotometer at a specific time and place. The method of bleaching substances in this study is split mouth and the selection of the mid-jaw treated as a randomized control or test, so that each patient randomly chooses a type of treatment for his half-jaw. The rendering of patients is done by another person who is not involved in the study, type of treatment, and control and testing groups.

Participants/Inclusion and exclusion criteria

Patients need to be treated for bleaching for which they are given this treatment so that the teeth that are needed to bleach for them are free of decay or repairs. Patients should be between 18 and 40 years old.

Intervention groups

Intervention group: Randomly selected half maxilla and bleaching gel containing 37/5% hydrogen peroxide in combination with 1% sodium hexametaphosphate. Control group: Randomly selected half maxilla and bleaching gel containing 37/5% hydrogen peroxide.

Main outcome variables

Dental sensitivity reported by patients before and during and immediately after the treatment, one month and three months after the treatment of office bleaching of the teeth and the degree of color stability.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180630040294N1**

Registration date: **2019-10-26, 1398/08/04**

Registration timing: **retrospective**

Last update: **2019-10-26, 1398/08/04**

Update count: **0**

Registration date

2019-10-26, 1398/08/04

Registrant information

Name

Mehrzad Khorshid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3768 1306

Email address

Khorshidm921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effects of bleaching gel containing 1% sodium hexametaphosphate on color stability and dental sensitivity during and after bleaching: a randomized, triangular blinded clinical trial study.

Public title

Evaluation and comparison of the effects of bleaching gel containing 1% sodium hexametaphosphate on color stability and dental sensitivity during and after bleaching: a randomized, triangular blinded clinical trial study.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients need to be treated for bleaching for which they are given this treatment so that the teeth that are needed to bleach for them are free of decay or repairs. Patients in favorable general and oral health conditions. Patients without dental sensitivity by touch and thermal stimuli.

Exclusion criteria:

Patients with a history of disease or long-term use of the drug.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual simple randomization with sealed envelope.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is performed on the same subjects, but in different parts of the body, they have two or more interventions, so that by random selection of an envelope, which half-jaw is the control and the other half is intervention. The data analyst is also a third party.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Science

Street address

Mashhad University of Medical Science, Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9185754934

Approval date

2018-11-21, 1397/08/30

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1397.082

Health conditions studied

1

Description of health condition studied

Bad teeth color

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Tooth color by spectrophotometer and tooth sensitivity by VAS system

Timepoint

Before and after treatment, immediately after treatment and 24 hours after treatment, one week after treatment, one month after treatment and 3 months after treatment.

Method of measurement

Tooth color by spectrophotometer and tooth sensitivity by VAS system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before initiation of study, a retractor will be used to retract the lips and cheeks. Then a light-polymerized opaldam (SDI, Australia) will be used to protect the gums and soft tissues. intervention group: the same bleaching gel as the control group with 1% sodium hexametaphosphate will be utilized for 30 minutes on other half of maxilla arch. After completion of

the bleaching period and removing the gel and resin dam a complete rinsing will be done.

Category

Treatment - Drugs

2

Description

Control group: control group: the Bleaching gel containing 37.5% hydrogen peroxide Polaooffice+ (SDI, Australia) will be applied for 30 minutes on randomly selected half of maxilla arch.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Science

Full name of responsible person

Mehrzad Khorshid

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamideh Sadat Mohammadipour

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Mashhad University of Medical Science, Azadi square, Vakil-Abad boulevard

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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

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

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**

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Full name of responsible person

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Student

Latest degree

Medical doctor

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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

The results of this study related to the main outcome at the end of the study released in a published article.

When the data will become available and for how long

About one year

To whom data/document is available

Anybody who needs the information.

Under which criteria data/document could be used

There was no specific conditions.

From where data/document is obtainable

By sending an email to Dr Hamideh Sadat Mohammadipour

What processes are involved for a request to access data/document

Immediately after receiving the email, it will response.

Comments