

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of efficacy and complications of several bleaching techniques on tooth discoloration following orthodontic treatment

Protocol summary

Study aim

The aim of the study was to compare the efficacy and potential complications of home-applied and in-office bleaching systems activated by different light sources in patients with discolored teeth after orthodontic treatment.

Design

The sample consisted of sixty volunteers with the chief complaint of tooth discoloration following orthodontic treatment. All the participants had discoloration in anterior maxillary teeth and their central incisors showed shade C2 or darker on the value-oriented shade guide. This study is a randomized single-blind clinical trial study.

Settings and conduct

The study was enrolled in the Department of Restorative Dentistry of Mashhad Dental School, Mashhad University of Medical Sciences, Mashhad, Iran. The study is single blind. (evaluator and statistician).

Participants/Inclusion and exclusion criteria

Volunteers referring to the Mashhad Dental School who have been past their orthodontic treatment for three months and have a clear color change in six anterior teeth. The exclusion criteria were patients who were pregnant or lactating; had moderate or severe discoloration resulting from pulpless teeth, tetracycline stains or fluorosis, as well as patients having smoking habits or those taking analgesic and anti-inflammatory drugs. Patients showing restored anterior teeth, non-carious cervical lesions, dental caries, periodontal disease or gingival recession, and subjects with previous tooth whitening procedures were also excluded from the sample.

Intervention groups

group 1 received home bleaching group 2 received in-office bleaching with the use of diode laser group 3 received in-office bleaching with the use of plasma arc group 4 received in-office bleaching without light source

Main outcome variables

Study group (by whitening method) Color change rate
Severity of pain and tooth sensitivity Complications after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180912041012N1**

Registration date: **2018-10-25, 1397/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-25, 1397/08/03**

Update count: **0**

Registration date

2018-10-25, 1397/08/03

Registrant information

Name

Salehe Sekandari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9501

Email address

sekandaris961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of efficacy and complications of several bleaching techniques on tooth discoloration following orthodontic treatment

Public title
Efficacy of several bleaching techniques following orthodontic treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have been past 3 months of their orthodontic treatment Significant tooth discoloration in the six anterior teeth
Exclusion criteria:
Severe internal discolorations (tetracycline, fluorosis) Periodontal disease Tooth decays or restorations Tooth sensitivity Gastrointestinal disease

Age
From **14 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The group allocation was achieved by computer-generated tables-using random block size of 4. The details of the allocated groups were written on cards and were kept in sequentially numbered, opaque, and sealed envelopes. These cards were prepared by an independent operator who was not involved in the research protocol.

Blinding (investigator's opinion)
Single blinded

Blinding description
The person evaluating the results of colorimetry and dental sensitivity ,complications and satisfaction of patients questionnaire and an the statistician was blind.

Placebo
Not 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 Sciences

Street address

At the beginning of the Vakil Abad Blvd., Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138735499

Approval date

2016-02-03, 1394/11/14

Ethics committee reference number

IR.mums.sd.REC.1394.84

Health conditions studied

1

Description of health condition studied

TOOTH DISCOLORATION

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Color change rate

Timepoint

Before treatment (T1), 1 hour after the end of the bleaching procedure(T2), and one week after the end of the bleaching procedure(T3).

Method of measurement

Spectrometer device

2

Description

Tooth sensitivity rate

Timepoint

Before treatment (T1), 1 hour after the end of the bleaching procedure(T2), and one week after the end of the bleaching procedure(T3).

Method of measurement

Visual Analogue Scale

3

Description

Incidence or absence of complications and patient satisfaction

Timepoint

One week after the end of the bleaching procedure

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Home bleaching

Category

Treatment - Other

2

Description

Intervention group: Laser-assistant in-office bleaching

Category

Treatment - Other

3

Description

Intervention group: Plasma arc-assistant in-office bleaching

Category

Treatment - Other

4

Description

Intervention group: Not light activated in-office bleaching

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dental School

Full name of responsible person

Salehe Sekandari

Street address

At the beginning of the Vakil Abad Blvd., Mashhad

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9177948959

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Email

sekandaris961@mums.ac.ir

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farzane Ahrari

Street address

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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

Salehe Sekandari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Salehe Sekandari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for updating data

Contact

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Full name of responsible person
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Position
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Other areas of specialty/work
Dentistry
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Tooth color evaluation date and complication questionnaire data

When the data will become available and for how long

6 month after Publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

For meta-analysis studies

From where data/document is obtainable

By Email sekandaris961@mums.ac.ir

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

About a month due to a review of the request by the authors

Comments