

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation the effect of polishing on enamel discoloration after the end of fixed orthodontic treatment

Protocol summary

Summary

The aim of this study is the enamel color change assessment at the end of the fixed orthodontic treatment and 10 weeks later after two different tooth cleaning techniques with using: carbide bur; carbide bur and polishing for remove remaining composite. This study is a randomized clinical trial and in a split mouth design. The samples are gathered from patients from executive office and two partners offices at 2016-2017. Inclusion criteria: intact central and lateral maxillary incisors; no tooth restoration; 12 to 35 years old patients; the patient at the end of fixed orthodontic treatment. Exclusion criteria: white spot lesion and restorative on maxillary central and lateral teeth; patient with poor oral hygiene. Sample size include 80 central and lateral incisors teeth (total of 160 teeth) on 40 patients. After the end of fixed orthodontic treatment the composite removes with carbide bur in both groups and in the intervention group in addition to removing composite with carbide bur, polishing does by Rubber cup and pumice (incisors and lateral in one side). The patients are not aware of the type of the instrument for removing composite and the polishing side but the clinician blinding is not possible. A comparison of color change between two groups in the period of 10 weeks does. This color change measure by the spectrophotometry device. Expected consequences is different discoloration between two groups after 10 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702219569N6**

Registration date: **2017-06-08, 1396/03/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-08, 1396/03/18

Registrant information

Name

Amir Mohammadi

Name of organization / entity

Department of Orthodontics of Dental Faculty of Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tabriz university of medical sciences

Expected recruitment start date

2016-11-30, 1395/09/10

Expected recruitment end date

2017-04-25, 1396/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of polishing on enamel discoloration after the end of fixed orthodontic treatment

Public title

Evaluation the effect of polishing on next discoloration of teeth at the end of fixed orthodontic treatment

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between 12-35; patients at the end of orthodontic treatment. Exclusion criteria: patients with crowns in four upper incisor teeth; patients with filling in the four upper incisor teeth; poor oral hygiene; patients with white spot lesion in four upper incisor teeth

Age

From **12 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randlist software use for randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Ethics Committee of Tabriz University of Medical Sciences.vice chancellor for research of Tabriz University of Medical Sciences ,Tabriz University of

City

Tabriz

Postal code

Approval date

2017-04-10, 1396/01/21

Ethics committee reference number

IR.TBZMED.REC.1396.1

Health conditions studied

1

Description of health condition studied

Check discolored teeth after the end of treatment

ICD-10 code

ICD-10 code description

2

Description of health condition studied

malocclusion

ICD-10 code

K07.4

ICD-10 code description

Anomalies of dental arch relationship

Primary outcomes

1

Description

Tooth discoloration

Timepoint

teeth discoloration after 10 weeks of its debonded

Method of measurement

spectrophotometry device

Secondary outcomes

1

Description

L,a,b parameters for tooth color

Timepoint

Immediately after and within 10 weeks of its debonded

Method of measurement

spectrophotometry

Intervention groups

1

Description

Control group: no intervention.

Category

Prevention

2

Description

Intervention group: polishing after the end of orthodontic treatment and remove the bracket for 30 seconds by rubber cup and pumice .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Executive's office

Full name of responsible person

Amir Mohamadi, Assistant professor

Street address

Eskan building, Abresan Crossroad

City

Tabriz

2

Recruitment center

Name of recruitment center

Partner office

Full name of responsible person

Human Sadr Hagigi, Assistant professor

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Azərbayjan building, 17 sharivar street

City

Tabriz

3

Recruitment center

Name of recruitment center

Partner office

Full name of responsible person

Arman Shayan, Assistant professor

Street address

Golgasht Threeway, Azadi street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tabriz university of medical sciences

Full name of responsible person

Mohammadreza Rashidi

Street address

Tabriz university of medical sciences, Golgasht street

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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

Vice chancellor for research of Tabriz university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Orthodontics of Dental Faculty of Tabriz University of Medical Sciences

Full name of responsible person

Amir Mohammadi

Position

Assistant professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of orthodontics of dental faculty of university of medical science

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Undergraduate dental students

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty