

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Studying tooth color alteration after fixed orthodontic treatment with two techniques of tungsten carbide bur and composite bur for composite removal in patients undergoing fixed orthodontic treatment

Protocol summary

Summary

The aim of the present clinical research is to study tooth color alteration after orthodontic treatment by removing the composite with two techniques of tungsten carbide bur and composite bur. The study will be done single blind in multiple centers on four anterior upper jaw teeth in 23 patients (92 tooth units). At the end of the orthodontic treatment debonding and composite removal will be done by two techniques of composite bur and tungsten carbide bur. Then tooth parameters will be measure by spectrophotometry right after debonding and two months afterward to determine the level of tooth color alteration. All patients undergoing the final stage of fixed orthodontic treatment are fit for the study. It is noteworthy to mention that the four anterior teeth have to be without any cavity and dental fillings. We hope that by studying tooth color alteration and color parameters in two groups of tungsten carbide bur and composite bur, we can obtain a technique that leads to minimal tooth color alteration level after orthodontic treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017013132323N1**

Registration date: **2017-04-04, 1396/01/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-04, 1396/01/15

Registrant information

Name

Amir Hooman Sadr Haghighi

Name of organization / entity

Tabriz university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2017-02-11, 1395/11/23

Expected recruitment end date

2017-08-03, 1396/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying tooth color alteration after fixed orthodontic treatment with two techniques of tungsten carbide bur and composite bur for composite removal in patients undergoing fixed orthodontic treatment

Public title

Tooth color alteration after orthodontic treatment

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: The existence intact maxillary central and lateral incisors restored after the fixed orthodontic;the patient's written informed consent to participate in the

study, which will be charged at the beginning Exclusion criteria: crown or filling in the maxillary anterior teeth; patients with White spot lesion in four maxillary anterior teeth ; Patients who have the history of trauma in maxillary anterior teeth; Patients who have root canal therapy in maxillary anterior teeth; patients with missing maxillary anterior teeth; Patients with poor oral health

Age

From **12 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

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 Medical Sciences, Golgasht Street Tabriz

City

Tabriz

Postal code

Approval date

2017-02-09, 1395/11/21

Ethics committee reference number

IR.TBZMED.REC.1395.1176

Health conditions studied

1

Description of health condition studied

Tooth color alteration after orthodontic treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Tooth discoloration

Timepoint

Right after deboding and two months afterward

Method of measurement

By spectrophotometry

Secondary outcomes

1

Description

Alteration of color parameters

Timepoint

Right after deboding and two months afterward

Method of measurement

By spectrophotometry

Intervention groups

1

Description

Tungsten carbide bur control group

Category

Prevention

2

Description

Composite bur intervention group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of orthodontics, Dentistry Faculty, Medical University of Tabriz

Full name of responsible person

Amir Hooman Sadr Haghighi

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Department of orthodontics, Dentistry Faculty, Medical University of Tabriz, Golgasht St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tabriz university of medical sciences

Full name of responsible person

Mohammad Rashidi

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Vice chancellor for research and technology, Medical University of Tabriz, Golgasht St.

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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**

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Web page address**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