

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of Durability of Esthetic Improvement of White Spot Lesions by Applying Resin Infiltration Technique

Protocol summary

Study aim

The aim of the study was to evaluate the color stability of white spot treated lesions with resin infiltration technique and its relation with their size.

Design

The clinical trial, not blind, single

Settings and conduct

The Restorative Department of Mashhad Dental School Patients

Participants/Inclusion and exclusion criteria

Inclusion criteria: The age range of participants was between 14 to 21 years Inactive, smooth and glossy labially lesions lesions in orthodontic patients who removed their brackets for 3 months Exclusion criteria: Active and cavitated lesions, Deciduous teeth, Restored teeth adjacent to white spots, Poor oral hygiene

Intervention groups

Application of resin infiltration technique on white spot lesions

Main outcome variables

The improvement of white spot lesions appearance also its durability, and decreasing their size followed by Resin Infiltration application

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180624040223N1**

Registration date: **2018-07-18, 1397/04/27**

Registration timing: **retrospective**

Last update: **2018-07-18, 1397/04/27**

Update count: **0**

Registration date

2018-07-18, 1397/04/27

Registrant information

Name

Roya Amiri Daluyi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3765 2020

Email address

Amiridr931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-04-08, 1395/01/20

Actual recruitment start date

2015-10-07, 1394/07/15

Actual recruitment end date

2016-04-08, 1395/01/20

Trial completion date

empty

Scientific title

Evaluation of Durability of Esthetic Improvement of White Spot Lesions by Applying Resin Infiltration Technique

Public title

Effect of Resin Infiltration Technique on White Spot Lesions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 14 to 21 years In active , smooth and glossy lesions in labial surface Lesions in orthodontic patients who removed their brackets for 3 months

Exclusion criteria:

Active and cavitated lesions Deciduous teeth Restored

teeth adjacent to white spot lesions Poor oral hygiene

Age

From **14 years** old to **21 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **18**

Actual sample size reached: **16**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Research Ethics Committee Of Mashhad Dental School

Street address

Vakil-Abad Blv, Mashhad Dental School

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2015-02-18, 1393/11/29

Ethics committee reference number

930116

Health conditions studied

1

Description of health condition studied

People with labial white spot lesions

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Color variation of lesions after treatment and in follow up sessions with the initial color

Timepoint

Before the intervention, immediately after the intervention, 1,3 and 6 months after intervention

Method of measurement

Spectrophotometer and Digital Camera

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Resin Infiltration (ICON) , DMG Company, Germany. 1 time application

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Restorative Department of Mashhad Dental School

Full name of responsible person

Alireza Boruzi Niyat

Street address

Vakil-Abad Blv, Mashhad Dental School

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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
Roya Amiri Daluyi

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Latest degree

Specialist

Other areas of specialty/work
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Person responsible for updating data

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Latest degree
Specialist

Other areas of specialty/work
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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