Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 decreaing 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
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Iran (Islamic Republic of)
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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 Infitration (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

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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
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Dentistry
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Person responsible for updating data

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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