

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of efficacy of resin infiltration in color stability of white spot lesions in labial surface of teeth; a clinical trial

#### Protocol summary

##### Summary

The aim of this study is to assess color stability during 6 months between white spot lesions and sound adjacent enamel areas after resin infiltration. This is a double-blind, non randomized trial. Patients with 57 anterior teeth who have white spot lesions- because of post orthodontic treatment or hypomineralization- are selected. The patients have 14 up 21 year-old. These teeth meet the following criteria: inactive lesions with smooth, shiny surface. Only the teeth longer than 3 months elapsed after debonding are selected to exclude those in active lesion state. Patients give informed consent before the start of the trial. During the trial, participants are given the same type of toothbrushes (Oral-B Classic Care, India) and dentifrices (Oral-B) for oral hygiene home care. The content of mineralization of lesions and its extension are determined using VistaCam ix camera. For the maximum protection of patients during treatment, the patients are made to wear the eye glasses, and rubber dam. The tooth surface is cleaned with a rubber cup and prophylaxis paste. All teeth are treated with icon resin infiltration according to manufacturer's recommendation. Standardized digital photographs are taken before, immediately after, and 1 month, 3 and 6 months after infiltration.. The difference (  $\Delta E$  ) in color between the sound enamel and lesions at each time is calculated with the measured CIE L\*a\*b\* values. A  $\Delta E > 3.7$  is considered a clinical indicator for color change

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014112720116N1**

Registration date: **2015-04-23, 1394/02/03**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-04-23, 1394/02/03

##### Registrant information

###### Name

Atoosa Talebi

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3883 2301

###### Email address

talebia911@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for Research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2015-04-20, 1394/01/31

##### Expected recruitment end date

2015-10-23, 1394/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of efficacy of resin infiltration in color stability of white spot lesions in labial surface of teeth; a clinical trial

##### Public title

Effect of resin infiltratin in color stability of white spot lesions in teeth

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: age between 14 up 21 year-old; having inactive labial white spot lesions with smooth and shiny surface; the teeth longer than 3 months elapsed after debonding( if it is because of orthodontic treatment).

Exclusion criteria: active lesions; cavited lesions; primary teeth; filled teeth; 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: **57**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not 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 Mashhad University of Medical Sciences

##### Street address

Ghoraishy Building, University st.

##### City

Mashhad

##### Postal code

#### Approval date

2015-02-18, 1393/11/29

#### Ethics committee reference number

930116

## Health conditions studied

### 1

#### Description of health condition studied

White Spot Lesions in Teeth

#### ICD-10 code

K02.0

## ICD-10 code description

White Spot Lesions

## Primary outcomes

### 1

#### Description

Color stability

#### Timepoint

before treatment, baseline, one month, three months, six months after treatment

#### Method of measurement

Spectrophotometry, digital photography.

## Secondary outcomes

### 1

#### Description

Color change

#### Timepoint

before treatment, baseline, one month, three months, six months after intervention

#### Method of measurement

Spectrophotometry, digital photography

## Intervention groups

### 1

#### Description

Intervention Group: white spot lesion in tooth

#### Category

Treatment - Drugs

### 2

#### Description

Control Group: the other point except white spot lesion in the same tooth

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Dentistry of Mashhad

##### Full name of responsible person

Dr. Mohammad Javad Moghaddas

##### Street address

##### City

Mashhad

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Vice chancellor for Research, Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Tafaghodi

**Street address**

Ghoraishi Building, University st.

**City**

Mashhad

**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, Mashhad 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**

School of Dentistry of Mashhad

**Full name of responsible person**

Mohammad Javad Moghaddas

**Position**

Associate Professor of Restorative Dentistry

**Other areas of specialty/work****Street address**

Restorative Department, School of Dentistry, Vakil Abad blvd., Azadi Sq.

**City**

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**Postal code**

91735

**Phone**

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moghaddasmj@mums.ac.ir

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate Professor of Restorative Dentistry

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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*