

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Effect of fluoride varnish, mouthwash, and Diode laser versus no intervention on enamel white spot lesions in orthodontic patients: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of fluoride varnish, mouthwash, and Diode laser versus no intervention on enamel white spot lesions in orthodontic patients

##### Design

This a randomized clinical trial, phase II, in which 60 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible orthodontic patients who will refer to School of Dentistry during the study period will be enrolled in the trial

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years Having bracket Enamel white spot lesions Exclusion criteria: Wide dental caries Inappropriate oral hygiene Systemic diseases Smoking A history of chemotherapy or radiotherapy A history of fluoride therapy in the last 3 months Pregnancy

##### Intervention groups

Intervention group 1: Covering tooth surface with fluoride varnish for 4 min and then Diode laser irradiation 980 nm, 1 w, 600 µm, once Intervention group 2: Covering tooth surface with fluoride varnish for 4 min once Intervention group 3: Using fluoride mouthwash 0.2% for 30 seconds once Control group: Just routine dental care without any intervention

##### Main outcome variables

Primary outcome: Assessing the enamel white spot lesions before intervention and then every month for three months through physical examination

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N219**

Registration date: **2018-05-05, 1397/02/15**

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

Last update: **2018-05-05, 1397/02/15**

Update count: **0**

##### Registration date

2018-05-05, 1397/02/15

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-16, 1396/12/25

##### Expected recruitment end date

2018-07-09, 1397/04/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of fluoride varnish, mouthwash, and Diode laser

versus no intervention on enamel white spot lesions in orthodontic patients: a randomized clinical trial

## Public title

Effect of fluoride varnish, mouthwash, and Diode laser versus no intervention on enamel white spot lesions in orthodontic patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age of 18 to 65 years Having bracket Enamel white spot lesions

### Exclusion criteria:

Wide dental caries Inappropriate oral hygiene Systemic diseases Smoking A history of chemotherapy or radiotherapy A history of fluoride therapy in the last 3 months Pregnancy

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random assignment of the patients to the intervention and control groups through drawing of lots

## 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 Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

##### Province

Hamadan

## Postal code

6517838695

## Approval date

2018-03-10, 1396/12/19

## Ethics committee reference number

IR.UMSHA.REC.1396.875

## Health conditions studied

### 1

#### Description of health condition studied

Orthodontic patients

#### ICD-10 code

Z46.4

#### ICD-10 code description

Encounter for fitting and adjustment of orthodontic device

## Primary outcomes

### 1

#### Description

Assessing the enamel white spot lesions

#### Timepoint

Before intervention and then every month for three months

#### Method of measurement

Through physical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Covering tooth surface with fluoride varnish for 4 min and then Diode laser irradiation 980 nm, 1 w, 600  $\mu$ m, once

#### Category

Treatment - Surgery

### 2

#### Description

Intervention group 2: Covering tooth surface with fluoride varnish for 4 min once

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group 3: Using fluoride mouthwash 0.2% for 30 seconds once

#### Category

Treatment - Drugs

#### 4

##### **Description**

Control group: Just routine dental care without any intervention

##### **Category**

N/A

#### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

School of Dentistry

###### **Full name of responsible person**

Dr Sara Ebrahimi

###### **Street address**

School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

###### **City**

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6517838695

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+98 81 3838 0572

###### **Email**

sara\_ebrahimi64@yahoo.com

#### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Hamedan University of Medical Sciences

###### **Full name of responsible person**

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

###### **Grant name**

###### **Grant code / Reference number**

###### **Is the source of funding the same sponsor organization/entity?**

Yes

###### **Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

###### **Full name of responsible person**

Dr Sara Ebrahimi

###### **Position**

Resident of Orthodontic

###### **Latest degree**

Medical doctor

###### **Other areas of specialty/work**

Dentistry

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#### **Person responsible for scientific inquiries**

##### **Contact**

###### **Name of organization / entity**

Hamedan University of Medical Sciences

###### **Full name of responsible person**

Dr. Sara Alijani

###### **Position**

Orthodontist

###### **Latest degree**

Medical doctor

###### **Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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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