# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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
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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 µm, 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
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## Sponsors / Funding sources

**1**

**Sponsor**
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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**
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
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Dr Sara Ebrahimi
**Position**
Resident of Orthodontic
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Ph.D.

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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