

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

A Clinical Trial of Comparing The effect of Fluoride varnish and Chlorhexidine gel on white spots and gingival indexes in orthodontic patients.

Protocol summary

Summary

The purpose of this study is to determine the effect of Chlorhexidine gel and Fluoride varnish on plaque and gingival indices and also their influence on white spots prevention in fixed orthodontics patients. The main Inclusion criteria is having a non-extraction orthodontic treatment and the main Exclusion criteria is the disability of performing hygienic instructions. In this study 40 patients will be divided into groups of 10 including: Chlorhexidine gel, Fluoride varnish, Control and Placebo. The type of study is double blind and randomization is done by table of random numbers. This is a single center clinical trial. Fluoride varnish is applied in one group, Chlorhexidine gel in the other and Placebo to the placebo group. The parameters will be measured four times in every 3 months in this manner: before first intervention, 3, 6 and 9 months after that. The parameters will be measured before the interventions in each time. The patients must have fix appliances in both jaws and need a Non-extraction treatment. The parameters that will evaluate include: gingival index, plaque index and white spot index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122531558N1**
Registration date: **2017-06-24, 1396/04/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-24, 1396/04/03

Registrant information

Name

Navid Yaraghi

Name of organization / entity

Isfahan University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical Trial of Comparing The effect of Fluoride varnish and Chlorhexidine gel on white spots and gingival indexes in orthodontic patients.

Public title

Effect of preventive agents on oral health in orthodontic patients.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age over 18; permanent dentition in

both jaws; Fixed appliances in both jaws at least 8 anterior teeth; Non extraction treatment. Exclusion criteria: Showing allergic reaction to used materials; history of previous orthodontic treatment; systemic disease affecting teeth such as Amelogenesis and Dentinogenesis Imperfecta; history of using drugs affecting plaque accumulation ,saliva secretion and gingiva; syndromes or systemic diseases associating with inflammatory processes (Licken planus,Lupus,Pemphigoid diseases); Patients who are not able to perform the hygiene instructions.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Azadi square, Isfahan

City

Isfahan

Postal code

81746-73461

Approval date

2016-01-30, 1394/11/10

Ethics committee reference number

IR.MUI.REC.1394.3.866

Health conditions studied

1

Description of health condition studied

Dental white spot lesion

ICD-10 code

K02.0

ICD-10 code description

Caries limited to enamel

2

Description of health condition studied

Gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

White spots

Timepoint

Before the first intervention, 3, 6 and 9 months after that and before the intervention in each time.

Method of measurement

Visual inspection with intra oral examination mirror

2

Description

Gingival index

Timepoint

Before the first intervention, 3, 6 and 9 months after that and before the intervention in each time.

Method of measurement

Dental probe

3

Description

plaque index

Timepoint

Before the first intervention, 3, 6 and 9 months after that and before the intervention in each time.

Method of measurement

Visual inspection

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Fluoride varnish %5 which is made in USA will be applied on teeth every 3 months until 9 months.

Category

Prevention

2

Description

Intervention group 2: Chlorhexidine gel 0/2% which is made in Spain, in dose of 5mg will be applied on teeth every 3 months until 9 months.

Category

Prevention

3

Description

Placebo group: Sorbitol solution (70% W/W) will be applied on teeth every 3 month until 9 months.

Category

Prevention

4

Description

Control group: No intervention is done.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontic department of Isfahan faculty of dentistry

Full name of responsible person

Navid Yaraghi(Orthodontics resident)

Street address

Faculty of dentistry, Hezar Jarib street, Azadi square, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr Omid Savabi

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Dental faculty, Isfahan University of Medical Sciences, Hezar Jarib street, Azadi square, Isfahan

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Isfahan

Grant name

30

Grant code / Reference number

394866

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

Yes

Title of funding source

Vice chancellor for research of Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Navid Yaraghi

Position

Orthodontics resident/Doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dental faculty of Isfahan University of Medical Sciences

Full name of responsible person

Dr Shiva Alavi

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Associate Professor

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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