

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Incidence of White Spot Lesions around Orthodontic Bands on First Permanent Molars after use of Two Glass Ionomer Cements

Protocol summary

Summary

In this randomized clinical trials 180 first permanent molars in patients that need to orthodontic band are chosen. The patients must have at least 2 first permanent molars and the teeth must be lack of caries and white spot(ws) lesion. The teeth are examined for caries and presence of WS lesions by visual inspection and also by using DIAGNOdent in 3 point at buccal and lingual side and data are recorded in information sheet. The teeth are cleaned, isolate and dry then orthodontic band are cemented to the teeth using GC Gold Label or GC Fuji Plus GI cements. Samples were divided into 3 groups and bands are removed after 6 months in group 1, 9 months in group 2 and 12 months in group 3. The teeth are then examined for caries and presence of WS lesions by visual inspection and by using DIAGNOdent.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406141882N4**
Registration date: **2014-07-04, 1393/04/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-04, 1393/04/13

Registrant information

Name

Masoud Fallahinejad Ghajari

Name of organization / entity

Faculty of Dentistry, Shahid Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Total cost of the project is paid by the Dental Research Center, Institute of Dental Sciences, Shahid Beheshti University of Medical Sciences.

Expected recruitment start date

2012-09-05, 1391/06/15

Expected recruitment end date

2013-01-04, 1391/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Incidence of White Spot Lesions around Orthodontic Bands on First Permanent Molars after use of Two Glass Ionomer Cements

Public title

White Spot Lesions Incidence around Orthodontic Bands

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: At least 2 permanent first molars; No whit spot lesion or similar lesions
Exclusion Criteria: Presence of Crack and fracture; Presence of caries and white spot

Age

From **6 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: 180

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Dental Research Center, Research Institute of Dental sciences, Shahid Beheshti University of Medical

Street address

Shahid Beheshti Dental School, Daneshjoo Bulv., Evin

City

Tehran

Postal code

Approval date

2012-07-09, 1391/04/19

Ethics committee reference number

جلسه 17

Health conditions studied

1

Description of health condition studied

White spot lesion

ICD-10 code

K02.0

ICD-10 code description

[Caries limited to enamel White spot lesions [initial caries]

Primary outcomes

1

Description

White spot lesio

Timepoint

Befor intervention, 6,9 and 12 months

Method of measurement

Observation and DIAGNOdent unit

Secondary outcomes

1

Description

White spot lesion

Timepoint

6, 9 and 12 months

Method of measurement

Observation and DIAGNOdent unit

Intervention groups

1

Description

Intervention group: GC Gold Label cement Controlled group: GC Fuji Plus cement

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Research Center, Institute of Dental Sciences, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Masoud Fallahinejad Ghajari

Street address

Dental school, Daneshjoo Blvd., Evin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental Research Center, Research Institute of Dental Sciences, Shahid Beheshti University of medical S

Full name of responsible person

Dr. Masoud Fallahinejad Ghajari

Street address

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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

Dental Research Center, Research Institute of Dental Sciences, Shahid Beheshti University of medical S

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

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Person responsible for general inquiries

Contact

Name of organization / entity

Dental Research Center, Institute of Dental Sciences,
Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr, Azam Naji Rad

Position

Pedodontist

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

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Person responsible for scientific inquiries

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Sciences

Full name of responsible person

Dr. Masoud Fallahinejad Ghajari

Position

Pedodontist/Associated Professor

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

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Person responsible for updating data

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

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Web page address

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