Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Facualty 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
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dental Research Center,Research Institute of Dental Siences, Shahid Beheshti University of medical S
Full name of responsible person
Dr. Masoud Fallahinejad Ghajari
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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 Siences, 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

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

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Person responsible for updating data

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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