

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Evaluation of bioactive glass particle adding to the glass ionomer cements in the accumulation of mutans and Lactobacillus around of orthodontic bands

#### Protocol summary

##### Summary

Objectives: Bioactive glass is used as an antibacterial agent. This study aimed to assess the effect of addition of BAG to glass ionomer cement on accumulation of Streptococcus mutans and Lactobacilli around orthodontic bands. Designing: This clinical trial was conducted on 10 patients requiring orthodontic treatment with lingual arch and molar bands. Method: In five patients, Fuji II SC GIC was used for cementation of the right and Fuji II SC containing 30wt% BAG was used for cementation of the left molar band. In the remaining five patients, Fuji II LC was used for cementation of the left and Fuji II SC containing 30wt% BAG was used for cementation of the right molar band. Inclusion criteria patient consent for participation in this study; good oral hygiene; absence of active caries or periodontal disease; no mouth breathing; absence of cleft lip or palate; absence of conditions affecting oral microbial flora; absence of conditions affecting tooth brushing and no use of chlorhexidine mouthwash or antibiotics within three weeks prior to this study or during the course of study. Exclusion criteria. Wash out of cement and loosening of appliances Main outcomes: Formation of S. mutans and Lactobacillus colonies in the culture medium was assessed and number of colonies was counted using a colony counter

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017061134451N1**

Registration date: **2017-07-08, 1396/04/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-07-08, 1396/04/17

##### Registrant information

###### Name

Maryam Shirazi

###### Name of organization / entity

Qazvin Dental school

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3335 3064

###### Email address

m.shirazi@qums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

##### Expected recruitment start date

2017-01-03, 1395/10/14

##### Expected recruitment end date

2017-03-05, 1395/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of bioactive glass particle adding to the glass ionomer cements in the accumulation of mutans and Lactobacillus around of orthodontic bands

##### Public title

Anti bacterial effect of bio active glass

##### Purpose

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria patient consent for participation in this study; good oral hygiene; absence of active caries or periodontal disease; no mouth breathing; absence of cleft lip or palate; absence of conditions affecting oral microbial flora; absence of conditions affecting tooth brushing and no use of chlorhexidine mouthwash or antibiotics within three weeks prior to this study or during the course of study. Exclusion criteria. Wash out of cement and loosening of appliances

### **Age**

No age limit

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **10**

### **Randomization (investigator's opinion)**

N/A

### **Randomization description**

### **Blinding (investigator's opinion)**

Single 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, Qazvin university of medical sciences

##### **Street address**

Qazvin University of Medical Sciences, Shahid Bahonar Blvd, Qazvin, Iran

##### **City**

Qazvin

##### **Postal code**

#### **Approval date**

2017-02-27, 1395/12/09

#### **Ethics committee reference number**

ir.qums.rec.1395.300

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Aggregation of bacteria

### **ICD-10 code**

K05.1

### **ICD-10 code description**

Chronic gingivitis

## **Primary outcomes**

### 1

#### **Description**

bio active glass

#### **Timepoint**

4 months

#### **Method of measurement**

sampling

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Cement without nano particle

#### **Category**

Prevention

### 2

#### **Description**

incorporation of nano particle in orthodontic cement

#### **Category**

Prevention

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Qazvin dental school

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

Maryam Shirazi

##### **Street address**

Qazvin University of Medical Sciences, Shahid Bahonar Blvd, Qazvin, Iran

##### **City**

Qazvin

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Vice chancellor for research, Qazvin University of Medical Sciences

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

Roya Naseh

**Street address**

Qazvin University of Medical Sciences, Shahid Bahonar Blvd, Qazvin, Iran

**City**

Qazvin

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Qazvin 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**

Qazvin university of medical sciences

**Full name of responsible person**

Maryam Shirazi

**Position**

Assistant professor

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

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Position**

Orthodontist

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Qazvin university of medical sciences

**Full name of responsible person**

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**Position**

Assistant professor

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

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**City**

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**Postal code**

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**Phone**

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**Fax****Email****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*