# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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
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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**
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**

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## Person responsible for scientific inquiries

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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*