

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### A clinical trial on the effects of topical fluoride, laser diode, and their combined application on the number of streptococcus mutans in saliva of 7- to 10-year-old children

#### Protocol summary

##### Summary

This study compares the effects of laser irradiation, fluoride therapy, and simultaneous application of them both on salivary levels of Streptococcus mutans. The study participants included 36 children without dental caries in mixed dentition who aged between 7 and 10 years. One school will be randomly selected from the list of schools in Birjand. Afterwards, 36 children will be selected from the school via systematic sampling method. The main inclusion criteria include non-use of antibiotics prior to visit, lack of medical history, and lack of either systemic or topical fluoride use (excluding toothpaste). Participants can leave the study any time in case they do not intend to continue participation. The children will be assigned into three 12-member groups via simple allocation method. Interventions will be performed in one center and in an unblinded manner. The first group receives 940 nanometer wavelength diode laser for 30 seconds on the buccal, lingual, palatal and dorsal surfaces. The second group receives fluoride therapy on all tooth surfaces using sodium fluoride varnish. The third group receives fluoride therapy and immediately after it, they will have diode laser. Saliva samples from each group will be taken and subsequently cultured before and 24 hours after intervention. Salivary levels of Streptococcus mutans in samples of the three groups will be compared with each other and with those before intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017061817756N20**  
Registration date: **2017-07-09, 1396/04/18**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-07-09, 1396/04/18

##### Registrant information

###### Name

Mohammad Bagher Roozgar

###### Name of organization / entity

Birjand University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 56 3239 5680

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mbroozgar@bums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-chancellery for Research, Birjand University of Medical Sciences

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2017-11-20, 1396/08/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial on the effects of topical fluoride, laser diode, and their combined application on the number of streptococcus mutans in saliva of 7- to 10-year-old children

**Public title**

Effects of fluoride and laser on streptococcus mutans

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Children aged 7 to 10 years without dental caries; non-use of antibiotics prior to visit; lack of medical history; lack of either systemic or topical fluoride use (excluding toothpaste). Exclusion criteria:

Unwillingness to cooperate in the study; not being in the mixed dentition stage.

**Age**

From **7 years** old to **10 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomization will be performed via random number tables.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Birjand University of Medical Sciences

**Street address**

Vice-chancellery for Research, Birjand University of Medical Sciences, Ghaffari St.,

**City**

Birjand,

**Postal code****Approval date**

2017-06-21, 1396/03/31

**Ethics committee reference number**

lr.bums.REC.1396.80

**Health conditions studied****1****Description of health condition studied**

Streptococcus mutans

**ICD-10 code**

B95.1

**ICD-10 code description**

Streptococcus, group B, as the cause of diseases classified to other chapters

**Primary outcomes****1****Description**

Streptococcus mutans level

**Timepoint**

Before and 24 hours after intervention

**Method of measurement**

Colony forming units

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention Group 2 (Fluoride Group): The members will receive fluoride therapy on all tooth surfaces using sodium fluoride varnish.

**Category**

Prevention

**2****Description**

Intervention Group 3 (Fluoride plus Diode Laser): The members will receive fluoride therapy and immediately after it, they will have 940 nanometer wavelength diode laser for 30 seconds on the buccal, lingual, palatal and dorsal surfaces.

**Category**

Prevention

**3****Description**

Intervention Group 1 (Laser Diode): The members will receive 940 nanometer wavelength diode laser for 30 seconds on the buccal, lingual, palatal and dorsal surfaces.

**Category**

Prevention

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**  
Booali Medical Complex  
**Full name of responsible person**  
Dr. Sohaila Darmiani  
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Abooreyhan St., Ghaffari Ave.,  
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rad.masoome71@gmail.com  
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## Person responsible for scientific inquiries

### Contact

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice-Chancellery for Research and Technology of Birjand University of Medical Sciences  
**Full name of responsible person**  
Dr. Tooba Kazemi  
**Street address**  
Vice-chancellery of Research and Technology, Birjand University of Medical Sciences, Ghaffari St.,  
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Birjand,  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Vice-Chancellery for Research and Technology of Birjand 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 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*