Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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+98 56 3239 5680

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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
Ir.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
Street address
Abooreyhan St., Ghaffari Ave.,
City
Birjand,

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 Reasearch and Technology, Birjand University of Medical Sciences, Ghaffari St.,
City
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
Name of organization / entity
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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