Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Nov 2026

Effect of Chitosan and Fluoride Varnish on Mutans Streptococcus levels in Saliva: a randomized clinical trial

Protocol summary

Study aim
The aim is to compare the effect of chitosan and fluoride varnishes on Streptococcus mutans count in saliva.

Design
parallel group, double blind, randomized controlled trial

Settings and conduct
Children are randomly divided into three groups of 30. Saliva samples are collected from three groups before the intervention and 24 hours after the intervention. In this study, participants and microbial analyzers and data analyzers are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: children without caries or primary caries within the age group of 4-6 years exclusion criteria: Children with a specific systemic disease or those who have had fluoride therapy in the last 6 months.

Intervention groups
Group I are treated with 5% chitosan varnish and group II received 3% chitosan varnish and group III (control) was treated with sodium fluoride varnish

Main outcome variables
The effect of chitosan varnish on plaque mutant streptococcus

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190925044878N1**
Registration date: **2020-12-22, 1399/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-22, 1399/10/02**
Update count: **0**

Registration date
2020-12-22, 1399/10/02

Registrant information

Name
Leila Basir

Name of organization / entity

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Iran (Islamic Republic of)

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+98 61 3338 9516

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basir-l@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-01-20, 1399/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Chitosan and Fluoride Varnish on Mutans Streptococcus levels in Saliva: a randomized clinical trial

Public title
Effect of Chitosan and Fluoride Varnish

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Children must be aged 4-6 years old. At the time of clinical examination, the teeth must be free of caries or have primary caries. Participants must have no history of taking antibiotics in the last month.

Exclusion criteria:
Children with a specific systemic disease Participants

who have had fluoride therapy in the last 6 months.

Age
From **4 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of randomization is simple, the unit of randomization is individual, and the tool of randomization is the table of random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, data analyzer, and microbial analyzer were doubled blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan boulvard

City
ahvaz

Province
Khouzestan

Postal code
61355-393

Approval date
2017-11-04, 1396/08/13

Ethics committee reference number
IR.AJUMS.REC.1396.592

Health conditions studied

1

Description of health condition studied
dental caries

ICD-10 code
K02

ICD-10 code description
Dental caries

Primary outcomes

1

Description
Streptococcus mutans count in saliva

Timepoint
before intervention and 24h after intervention

Method of measurement
sterile tubes

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: 30 children for whom chitosan 5% varnish will be used.

Category
Other

2

Description
Intervention group 2: 30 children for whom Chitosan 3% varnish will be used.

Category
Other

3

Description
Control group: 30 children for whom the standard Sodium Flouride varnish will be used.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
School of dentistry, Ahvaz jundishapur university of medical science

Full name of responsible person
Leila Basir

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school of dentistry, Ahvaz Jundishapur university of

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Sponsors / Funding sources

1

Sponsor
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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
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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Position
Associated professor
Latest degree
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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)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable