Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Nov 2026

The effect of 20 ppm ozonated gel and 1 % chlorhexidine gel on plaque index and the number of Streptococcus mutans obtained from dental plaque in children aged 6-12 years: A double-blind randomized clinical trial study

Protocol summary

Study aim
The effect of 20 ppm ozonated gel and 1 % chlorhexidine gel on plaque index and the number of Streptococcus mutans obtained from dental plaque in children aged 6-12 years: A double-blind randomized clinical trial study

Design
A clinical trial with parallel intervention groups, double-blind, randomized, phase two on 165 patients. The sampling method is random. Randomization using a table of random numbers is the Random Allocation Software.

Settings and conduct
Among the children aged 6-12 years referring to Tabriz Dental Faculty, they participated in the study. All people will be trained in oral hygiene and the plaque index will be calculated. Patients are randomly assigned to one of the groups. In the first intervention group, 20 ppm ozone gel and in the second intervention group, 1% chlorhexidine gel are applied twice a day (morning and night) half an hour after meals for 3 weeks using a finger on all dental surfaces. In the third group, People will rub their clean finger on all tooth surfaces. After three weeks, the final plaque index will be calculated. The patient is aware of the existence of several types of treatment but does not know which group he is in. The evaluators of the plaque index are not aware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Have not been treated with antibiotics in the last 3 weeks. People with high caries risk (dmft above 3) Exclusion criteria: Unwillingness to cooperate in the sampling process at the specified time, Appearance of allergy symptoms to the substances used in the study, Failure to follow the instructions given

Intervention groups
Intervention 1: Ozonated gel 20 ppm - Intervention 2: Chlorhexidine gel 1% - Control: No use of gel

Main outcome variables
The plaque index Number of Streptococcus mutans bacteria

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220727055562N1**
Registration date: **2022-08-15, 1401/05/24**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-15, 1401/05/24**
Update count: **0**

Registration date
2022-08-15, 1401/05/24

Registrant information

Name
Zahra Molaei Qaramaleki

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-13, 1401/05/22

Expected recruitment end date

2022-11-20, 1401/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 20 ppm ozonated gel and 1 % chlorhexidine gel on plaque index and the number of Streptococcus mutans obtained from dental plaque in children aged 6-12 years: A double-blind randomized clinical trial study

Public title

The effect of the ozonated gel on children's dental plaque

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 6 to 12 years Being healthy in the state of systemic condition No known allergies Consent to participate in the study

Exclusion criteria:

History of allergy to chlorhexidine or ozone Antibiotic use in the past few months Children with mental and physical disabilities History of frequent food and drug allergies

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **165**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sampling will be done among the patients referred to Tabriz Dental Faculty who are eligible for the study. The randomization method is simple and its unit is individual. Our tool for randomizing a table of random numbers. Based on this, the type of treatment is marked with code A (20 ppm ozone gel), B (1% chlorhexidine gel), and C (control) and placed inside sealed envelopes. Then the envelopes are placed in a bag and mixed. Then it is randomly selected from the bag and treatment is given to the patient by observing the code. In order to avoid selection bias, the random assignment of people to the study groups will be concealed and will remain hidden until the interventions are carried out. None of the patients will be informed about the treatment of another patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind. Patients are aware of the existence of some types of treatment, but they do not know which group they belong to. After preparation, the gels will be transferred to containers with the same shape and packaging and will be labeled, and only the code of the gels will be recorded on the label (blinding of the treatable people) and only one of the collaborators of the project will know the content of the gels and he knows how to allocate the patients in the groups, he will distribute the gels among the patients, and the examination and taking of plaque samples will be done by another colleague of the project who does not know the type of patient group (blinding of the treating people).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Golgasht St., Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2022-06-27, 1401/04/06

Ethics committee reference number

IR.TBZMED.REC.1401.304

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

Plaque index

Timepoint

Once before the start of the intervention and the second time after three weeks (at the end of the intervention).

Method of measurement

After people use the detector tablet, the amount of plaque index is calculated and recorded.

2

Description

Number of Streptococcus mutans bacteria

Timepoint

Once before the start of the intervention and the second time after three weeks (at the end of the intervention).

Method of measurement

The dental plaque sample will be removed from all surfaces of the desired tooth using a sterile toothpick and will be transferred to the microbiology laboratory and cultured in the Agar medium. The number of bacterial colonies is counted.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: O3life 20 ppm ozonated gel is applied twice a day (morning and night) half an hour after meals for 3 weeks using a finger on all dental surfaces. After three weeks, the final plaque index and the number of Streptococcus mutans bacteria will be calculated.

Category

Treatment - Drugs

2

Description

The second intervention group: HEXIGEL 1% chlorhexidine gel is applied twice a day (morning and night) half an hour after meals for 3 weeks using a finger on all dental surfaces. After three weeks, the final plaque index and the number of Streptococcus mutans bacteria will be counted.

Category

Treatment - Drugs

3

Description

Control group: The patient's clean finger is rubbed twice a day (morning and night) half an hour after meals for 3 weeks on all dental surfaces. After three weeks, the final plaque index and the number of Streptococcus mutans bacteria will be calculated.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tabriz

Full name of responsible person

Ziya Ebrahim Adhami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Ziya Ebrahim Adhami
Position
Assistant Professor
Latest degree
Specialist
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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
Not applicable
Data Dictionary
Not applicable