

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3287 8879

##### Email address

zahra.molayi@gmail.com

##### 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

##### **Street address**

Golgasht St., Tabriz University of Medical Sciences

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

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##### **Phone**

+98 44 3344 4598

##### **Email**

adhamipedodontist@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Mozhgan Kachuei

##### **Street address**

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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

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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Ziya Ebrahim Adhami

**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Ziya Ebrahim Adhami

**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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**Phone**

## 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