Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of ozone on decalcified points OF ENAMEl

Protocol summary

Summary
A total of 20 subjects, (40 lesions), each with two initial caries, will be recruited. The two lesions in each subject will randomly be assigned for treatment with ozone and remineralization agent and only remineralization agent, in a double-blind design, in a general dental practice. Subjects will be recalled at 1st and 3rd months. The system used to evaluate the effect of ozone is DIAGNOdent. Enamel surfaces will be cleaned by profilaxy gel before using the equipment. Machine will be calibrated by use of healthy enamel.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT138809222844N1**
Registration date: **2010-03-18, 1388/12/27**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2010-03-18, 1388/12/27

Registrant information
Name
Amir Mirmoezzi
Name of organization / entity
Shahid Beheshti dental university, Shahid Beheshti university of medical sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source
Research Center of Shahid Beheshti dental university

Expected recruitment start date
2009-09-30, 1388/07/08
Expected recruitment end date
2010-01-31, 1388/11/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of ozone on decalcified points OF ENAMEl

Public title
Effect of ozone on tooth
Purpose
Treatment
Inclusion/Exclusion criteria
Having active initial caries on both sides
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Council of Research Center of Shahid Beheshti dental university

Street address

Shahid Beheshti Dental university, Velenjak, TEHRAN, IRAN

City

Tehran

Postal code

Approval date

2009-12-08, 1388/09/17

Ethics committee reference number

8807/ا.ك.م

Health conditions studied

1

Description of health condition studied

Initial caries

ICD-10 code

K02.0

ICD-10 code description

Caries limited to enamel White spot lesions [initial caries]

Primary outcomes

1

Description

Change of diagnodent number in patients

Timepoint

after 4 months

Method of measurement

diagnodent

Secondary outcomes

1

Description

Arresting or reversing the progression of dental caries

Timepoint

after 7 months

Method of measurement

by using diagnodent

Intervention groups

1

Description

Usage of ozotop unit (140ppm 12 seconds 2 Times) and remineralization agent for 3 minutes in intervention group

Category

Treatment - Devices

2

Description

Usage of remineralization agent in control group for 3 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti dental university

Full name of responsible person

Street address

Velenjak

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti dental university, Dental research center

Full name of responsible person

Dr.Seyed Mohammad Reza Safavi

Street address

Velenjak

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti dental university, Dental research center

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
Shahid Beheshti dental university
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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