

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the Success of Ozone gel as capping material between two appointments in the pulpectomy of necrotic primary molar teeth

Protocol summary

Study aim

Evaluation of the Success of Ozone gel as capping material between two appointments in the pulpectomy of necrotic primary molar teeth

Design

Clinical trials, with Parallel Groups, single-blinded and Randomized. Sampling Method is random. The randomization Method is simple and our Tool for randomization is randomized Number Chart. 56 people were divided into two groups. The control group, normal pulpotomy using formocresol as a pulp covering material between two sessions in pulpectomy of the primary molar necrosis and the test group will receive ozone as a pulp covering material between two sessions. The two groups will ultimately fill the root canals with ZOE material as the final filling material of the canal.

Settings and conduct

The study will be performed in the pediatric department, Tabriz Dental School. The ozone-impregnated cotton ball will be placed in a pulp chamber at a concentration of 1: 5. During the second session, the teeth will be isolated with Rubber Dam and the cotton bullet will be removed. In the control group, all the steps performed for the test group will be repeated, except that formocresol will be used as a pulp covering agent between two sessions. A pediatrician who is unaware of the type of treatment (single-blind) will be examined during a 6-month-long follow-up.

Participants/Inclusion and exclusion criteria

Entrance criteria: ages 4 to 8 years with primary molar necrosis with intraoral enlarged vestibular Entrance criteria: Favism- hyperthyroidism -Anemia -Ozone sensitivity Hemorrhagic disease

Intervention groups

Control group, normal pulpotomy using formocresol as a pulp covering material between two sessions in pulpectomy of the primary molar necrosis and the test group will receive ozone as a pulp covering material between two sessions.

Main outcome variables

Clinical success; Radiographic success

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190514043585N1**

Registration date: **2019-05-25, 1398/03/04**

Registration timing: **retrospective**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Seyedeharezou Ghoreyshizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3330 8948

Email address

ghoreyshizadeha@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-05-10, 1398/02/20

Actual recruitment start date

2018-12-11, 1397/09/20

Actual recruitment end date

2019-05-10, 1398/02/20

Trial completion date

2019-05-10, 1398/02/20

Scientific title

Evaluation of the Success of Ozone gel as capping material between two appointments in the pulpectomy of necrotic primary molar teeth

Public title

Evaluation of the Success of Ozone gel in the pulpectomy of necrotic primary molar teeth

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

ages 4 to 8 years The ability to cooperation for treatment The deciduous molar necrosis with intraoral enlarged vestibular (without drainage) having primary radiography with a very high mild PDL in radiography parental satisfaction for participation in the study

Exclusion criteria:

Deficiency of glucose 6 phosphate dehydrogenase or favism hyperthyroidism Anemia Ozone sensitivity Hemorrhagic disease deciduous molars with irreparable crown Mobility and movement greater than 1 mm Existence of internal or external analysis in radiography Root less than 3/2

Age

From **4 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **56**

Actual sample size reached: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling Method is randomly Available among Individuals referring to pediatric Department of Tabriz Dental faculty. The randomization Method is simple and the Unit is individual, our Tool for randomization is the randomized Number Chart. Furthermore, the Allocation of treatment to Patients is done Randomly. To do this, the types of treatment are identified with code A (control) and B (case) and then the sealed in Envelopes that will be placed in a Box and stirred. Then they are randomly chosen from the Box and after observing the code, the treatment is given to the Patient. None of the Patients will be informed about another Patient's treatment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants do not know that different types of treatment are being studied. They are also totally blinded to the information of the other Participants.

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

Floor2, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2019-05-16, 1398/02/26

Ethics committee reference number

IR.TBZMED.REC.1398.063

Health conditions studied**1****Description of health condition studied**

Necrotized primery molars

ICD-10 code

K02.5

ICD-10 code description

Caries with pulp exposure

Primary outcomes**1****Description**

Clinical success

Timepoint

6 months

Method of measurement

A checklist containing information -1 No pain, 2-No sensitivity to Percussion 3-Missing or increased mobility 4- No opening of the sinus 5. No withdrawal of pushy exudates from the gingival margin

2**Description**

Radiological success

Timepoint

6 months

Method of measurement

Radiography and completing the checklist 1 - Radiolucency has not been created in the periapical or fork 2. There are no symptoms of internal and external resorption.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Normal pulpectomy using formocresol as a pulp covering agent between two sessions in pulpectomy of primary molar necrosis

Category

Treatment - Drugs

2

Description

Intervention group: pulpectomy using ozone as a pulp covering agent between two sessions in pulpectomy of primary molar necrosis

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Department, Faculty of Dentistry, Tabriz

Full name of responsible person

Seyedeh Arezou Ghoreyshizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Prof. Abolghasem Jouyban

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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

Seyedeh Arezou Ghoreyshizadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Seyedeh Arezou Ghoreyshizadeh

Position

Associate 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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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