

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of the effect of ozon gel on the clinical and radiographic success rate of partial pulpectomy of primary molars with irreversible pulpitis

Protocol summary

Study aim

Evaluation of the effect of ozon gel on the clinical and radiographic success rate of partial pulpectomy of primary molars with irreversible pulpitis

Design

Clinical trials, with Parallel Groups, single-blinded and Randomized and sampling method is random. The randomization method is simple and with number Chart. 50 people were selected and one tooth per person was considered as a control and another tooth was considered for treatment. Control tooth, dental restoration with amalgam or with ssc and test teeth will be disinfected with a paper soaked in ozone gel. The channels will be filled with ZOE.

Settings and conduct

The study will be performed in the pediatric department, Tabriz Dental School. Control tooth, dental restoration with amalgam or with ssc and test teeth will be disinfected with a paper soaked in ozone gel. The channels will be filled with ZOE. A pediatrician who is unaware of the type of treatment (single- blind) will be examined during a 6-month-long followup.

Participants/Inclusion and exclusion criteria

Entrance : Ages 4 to 8 years- Double sided molar with irreversible pulpitis requires pulpectomy- -Lack of symptoms of external root resorption-Possibility of crow restoration Entrance: Favism- hyperthyroidism -Anemia - Ozone sensitivity- Hemorrhagic disease

Intervention groups

Intervention: The canals will be disinfected with a paper soaked in ozone gel. The channels will be filled with ZOE. Control: All steps performed for the test group will be repeated, except that only routine canal washing solutions containing 1% hypochlorite and normal saline will be used. Eventually, the tooth crown will be restored with amalgam or ssc.

Main outcome variables

Clinical success; Radiographic success

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190514043585N2**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

Registration date

2020-06-29, 1399/04/09

Registrant information

Name

Seyedeharezou Ghoreyshizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3330 8948

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-29, 1399/04/09

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of ozon gel on the clinical and radiographic success rate of partial pulpectomy of primary molars with irreversible pulpitis

Public title

Evaluation of the effect of ozon gel on the clinical and radiographic success rate of

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages 4 to 8 years The ability to cooperation for treatment Double sided molar with irreversible pulpitis requires pulpectomy Having primary radiography Lack of symptoms of necrosis in radiography Lack of symptoms of external root resorption in radiography Possibility of crown restoration Parental satisfaction for participation in the study

Exclusion criteria:

Deficiency of glucose 6 phosphate dehydrogenase or favism Hyperthyroidism Anemia Ozone sensitivity Hemorrhagic disease

AgeFrom **4 years** old to **8 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **100**

More than 1 sample in each individual

Number of samples in each individual: **2**

In 50 children who require partial pulpectomy of bilateral first molar or partial pulpectomy of bilateral second molar in the maxilla or mandible

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 . 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. One person's tooth was considered as a control and another tooth for treatment.

Blinding (investigator's opinion)

Single blinded

Blinding description

The pediatrician is unaware of the outcome of the treatment and the type of disinfectant used for each

patient.

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

2020-06-08, 1399/03/19

Ethics committee reference number

IR.TBZMED.REC.1399.233

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**

Intervention group: Disinfection of canal by ozon gel

Category

Treatment - Other

2**Description**

Control group: Disinfection of canal by routine canal washing solutions containing 1% hypochlorite and normal saline

Category

Treatment - Other

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**

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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

Seyedeh Arezou Ghoreyshizadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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