Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of ozone gel on the clinical and radiographic success of ferric sulfate primary molar pulpotomy

Protocol summary

Study aim

Evaluation of the effect of ozone gel on the clinical and radiographic success of primary molars pulpotomy with ferric sulfate

Design

A clinical trial with the parallel intervention group, one-way blind, randomized, random sampling method. The randomization method is simple and with a random number table. Twenty-five patients were selected and one tooth per person was considered as a control and the other tooth was considered for treatment. In the control group, normal pulpotomy using 15.5% ferric sulfate, and in the experimental group, ozone gel will be used as a disinfectant before chamber ferric sulfate. In both groups, they will eventually be treated with Zonalin and the final restoration of the crown will be done with SSC.

Settings and conduct

The study will be performed in the pediatric department, Tabriz Dental School. Control teeth, normal pulpotomy using 15.5% ferric sulfate, and test teeth ozone gel will be used as a disinfectant before the ferric sulfate chamber. Evaluation of treatment success by a pediatric dentist who is unaware of the type of treatment (one-blind) will be assessed during a 6-month follow-up.

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. Exit: Favism- hyperthyroidism -Anemia -Ozone sensitivity- Hemorrhagic disease

Intervention groups

In the control group, normal pulpotomy using 15.5% ferric sulfate, and in the experimental group, ozone gel will be used as a disinfectant before chamber ferric sulfate. In both groups, they will eventually be treated with Zonalin and the final restoration of the crown will be done with SSC.

Main outcome variables

Clinical success

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190514043585N3**
Registration date: **2021-12-29, 1400/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-29, 1400/10/08**
Update count: **0**

Registration date

2021-12-29, 1400/10/08

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

2021-12-28, 1400/10/07

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of ozone gel on the clinical and radiographic success of ferric sulfate primary molar pulpotomy

Public title
Evaluation of the effect of ozone gel on the clinical and radiographic success of ferric sulfate primary molar pulpotomy

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 Lack of symptoms of necrosis or inflammation of the root pulp in radiography Lack of symptoms of external root resorption in radiography Having primary 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

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

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **25**
More than 1 sample in each individual
Number of samples in each individual: **2**
In 25 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
The sampling method is randomly Available among Individuals referring to the 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 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
2021-08-30, 1400/06/08

Ethics committee reference number
IR.TBZMED.REC.1400.514

Health conditions studied

1

Description of health condition studied
Primary tooth caries

ICD-10 code
K02

ICD-10 code description
Dental caries

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

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the experimental group, the procedure will be as follows: The desired tooth will be anesthetized and isolated with a Rubber Dam. After removing all caries and debris, an access cavity will be created. The contents of the coronary pulp tissue will be removed and then ozone gel (Vitomex) will be placed for disinfection After a few minutes of melting the gel, 15.5% ferric sulfate (UltraDent Astingedent) is placed in place and finally, zonalin (Zoliran) will be applied. and the final restoration will be done in the same meeting. This gel can stay at room temperature for months, but to maintain the highest performance, it must be stored in the refrigerator at 15 degrees Celsius or less. All steps will be performed by the student participating in the study under the supervision of the supervisor. Clinical success will be assessed by a pediatrician during a 6-month clinical follow-up. The pediatrician is unaware of the type of treatment given to each patient.

Category

Treatment - Other

2

Description

Control group: Normal pulpotomy using ferric sulfate. In the control group, the procedure will be as follows: The desired tooth will be anesthetized and isolated with a Rubber Dam. After removing all caries and debris, an access cavity will be created. The contents of the coronal pulp tissue will be extracted. 15.5% ferric sulfate (UltraDent Astingedent) will be placed in place and finally, zonalin (Zoliran) will be placed and the final repair will be done in the same session. In the control group, all the steps performed for the experimental group will be repeated, except Ozone gel will not be used for disinfection and eventually the crown of the teeth will be regenerated. All steps will be performed by the student participating in the study under the supervision of the supervisor. Clinical success will be assessed by a pediatrician during a 6-month clinical follow-up. The pediatrician is unaware of the type of treatment given to each patient.

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
Parviz Shahabi

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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
Ph.D.

Other areas of specialty/work
Dentistry
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Person responsible for updating data

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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