

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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 crown 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	treatment and the type of disinfectant used for each patient.
Scientific title	Placebo
Evaluation of the effect of ozone gel on the clinical and radiographic success of ferric sulfate primary molar pulpotomy	Not used
Public title	Assignment
Evaluation of the effect of ozone gel on the clinical and radiographic success of ferric sulfate primary molar pulpotomy	Parallel
Purpose	Other design features
Treatment	
Inclusion/Exclusion criteria	Secondary Ids
Inclusion criteria:	empty
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	Ethics committees
Exclusion criteria:	1
Deficiency of glucose 6 phosphate dehydrogenase or favism Hyperthyroidism Anemia Ozone sensitivity Hemorrhagic disease	Ethics committee
Age	Name of ethics committee
From 4 years old to 8 years old	Ethics committee of Tabriz University of Medical Sciences
Gender	Street address
Both	Floor2, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St
Phase	City
N/A	Tabriz
Groups that have been masked	Province
• Outcome assessor	East Azarbaijan
Sample size	Postal code
Target sample size: 25	5166614711
More than 1 sample in each individual	Approval date
Number of samples in each individual: 2	2021-08-30, 1400/06/08
In 25 children who require partial pulpectomy of bilateral first molar or partial pulpectomy of bilateral second molar in the maxilla or mandible.	Ethics committee reference number
Randomization (investigator's opinion)	IR.TBZMED.REC.1400.514
Randomized	
Randomization description	Health conditions studied
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.	1
Blinding (investigator's opinion)	Description of health condition studied
Single blinded	Primary tooth caries
Blinding description	ICD-10 code
The pediatrician is unaware of the outcome of the	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

Street address

Tabriz University of Medical Sciences, Golgasht St.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

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

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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 scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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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