

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of effect of ferric sulfate & formocresol on clinical & radiographic success of primary molars pulpotomy -48 months follow up

Protocol summary

Study aim

Determination of the effect of ferric sulfate and formocresol on the clinical and radiographic success of pulpotomy in primary molars in 4-7 year-old children referring to the private clinic during 48 months follow up every 6 months

Design

In this research, 50 healthy children aged 4-7 year-old had a decayed primary molars on both sides of the upper or lower jaw were chosen purposefully and teeth were randomly divided in two control and intervention groups

Settings and conduct

In this research, 50 healthy children aged 4-7 old had a decayed primary molars on both sides of the upper or lower jaw were chosen purposefully and teeth were randomly divided in two control and intervention groups. A pulpotomy technique is performed at a meeting by a pediatrician in a private clinic. In order to complete the pulpotomy in each side of the mouth, the patient should be randomly assigned to one session of sterilized cotton padded with formocresol for 5 minutes and another session with a ferric sulfate applicator for 30 seconds.

Participants/Inclusion and exclusion criteria

Entry conditions: 1) Having at least one decayed molar on each mandibular or maxillary jaw 2) Absence pulp degeneration (swelling, mobility, spontaneous pain, sinus tract, fistula or abscess) 3) Absence radiographic symptoms such as internal and external resorption, pathologic lesions in the formation area, pulp stone, PDL widening 4) Pulp exposure during caries removal 5) Can be restored with amalgam or SSC
Conditions of non-entry: primary molar with superficial caries

Intervention groups

In the intervention group, ferric sulfate and in the control group, formocresol is used

Main outcome variables

In this study evaluate the effect of ferric sulfate as a substitute of formocresol in treatment of primary molars.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161119030971N2**

Registration date: **2018-03-13, 1396/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-13, 1396/12/22**

Update count: **0**

Registration date

2018-03-13, 1396/12/22

Registrant information

Name

Nahid Askarizadeh

Name of organization / entity

Dental branch, Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 21225645713

Email address

n_asgarizadeh@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-22, 1396/11/02

Expected recruitment end date

2018-06-13, 1397/03/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of ferric sulfate & formocresol on clinical & radiographic success of primary molars pulpotomy -48 months follow up

Public title

primary molars pulpotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having at least one decayed molar on each mandibular or maxillary jaw
Absence pulp degeneration (swelling, mobility, spontaneous pain, sinus tract, fistula or abscess)
Absence radiographic symptoms such as internal and external resorption, pathologic lesions in the forcation area, pulp stone, PDL widening
Pulp exposure during caries removal
Can be restored with amalgam or SSC
Conditions of non-entry

Exclusion criteria:

primary molar with superficial caries

Age

From **4 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

More than 1 sample in each individual

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

decayed primary molar with pulpotomy treatment on either maxillary or lower jaw

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomized, randomized numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

the patient does not know which material is being used
the evaluator while clinical & radiographic evaluation
does not know

Placebo

Not used

Assignment

Parallel

Other design features

Long term follow up

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

دانشکده دندانپزشکی دانشگاه آزاد اسلامی تهران

Street address

Neyestan 10, Pasdaran, Tehran

City

tehran

Province

Tehran

Postal code

19585/175

Approval date

2016-12-20, 1395/09/30

Ethics committee reference number

IR.IAU.DENTAL.REC.1396,34

Health conditions studied

1

Description of health condition studied

Evaluation the effect of ferric sulfate in treatment of pulpotomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Clinical success

Timepoint

6 months for 48 months

Method of measurement

clinical observation

2

Description

Radiographic success

Timepoint

6 months for 48 months

Method of measurement

Radiographic observation

Secondary outcomes

empty

Intervention groups

1

Description

In this group, ferric sulfate will be used once for 30 seconds.

Category

Treatment - Drugs

2

Description

Control group: diluted formocresol solution(1:5)(sultan inc) once for 5 minutes will be used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

مطب خصوصی

Full name of responsible person

دکتر ناهید عسکری زاده

Street address

NO. 81, West jamal Ave, Vafamanesh, Heravi Sq, Tehran Town

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Nahidaskarizadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Private office

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

Private office

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Private Office

Full name of responsible person

Dr Nahid Askarizadeh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

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