

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

comparison of success rate of ferric sulfate and sodium hypochlorite for primary molar teeth pulpotomy in 5-8 years children .

Protocol summary

Summary

Currently the most common material used in primary molar pulpotomy is ferric sulfate and formocresol. But the usefulness of formocresol has been questionable due to its systemic toxicity. Despite the clinical success of ferric sulfate and formocresol, histological studies, have shown a severe inflammatory response. An alternative to pulpotomy is sodium hypochlorite that is a good antimicrobial agent without significant irritation to pulp. and sodium hypochlorite, is a hemostating factor, and the most critical factor for clinical success in pulpotomy procedure. The aim of this study is to compare the clinical and radiographic success rate of ferric sulfate and sodium hypochlorite pulpotomy in primary molars. In the initial evaluation of these teeth, there should be no pulpotomy contraindications . otherwise the patient will be excluded. In this study children 5-8 years old with at least two primary second molars needs pulpotomy, will be studied. This study is a double blind randomized clinical trial. Teeth are pulpotomized and dried with sterile cotton pellets placed in the pulp chamber for 5 minutes. In case of continuous bleeding, tooth is excluded from study. If bleeding stopped, study in two groups continues. Group1: pulpotomy with ferric sulfate 15.5% ,Group2: pulpotomy with 5% sodium hypochlorite, which is placed in the cavity. Then in both groups Zinc Oxide Eugenol is placed as a base and then restore with stainless steel crown. The number of samples examined in this study is 60, 30 in ferrous sulfate group and 30 in sodium hypochlorite group. The teeth will be assessed for clinical and radiographic success for a period of 6 and 12 months .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100711028N1**

Registration date: **2013-05-20, 1392/02/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-20, 1392/02/30

Registrant information

Name

Zahra Dehghan

Name of organization / entity

Islamic Azad University khorasgan Branch

Country

Iran (Islamic Republic of)

Phone

+98 31 1673 3103

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University khorasgan Branch

Expected recruitment start date

2013-05-12, 1392/02/22

Expected recruitment end date

2013-06-12, 1392/03/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of success rate of ferric sulfate and sodium hypochlorite for primary molar teeth pulpotomy in 5-8 years children .

Public title

sodium hypochlorite pulpotomy success in primary molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children 5-8 years old; presence of at least 2 primary second molars teeth in mandible requiring pulpotomy. Exclusion criteria: Children over 8 years; Absence of two primary second molars in mandible; pulpotomy contraindications of primary molars including: nocturnal pain; presence of fistulas; abscesses, internal and external root resorption; periapical lucency; furcal lucency; Continuous bleeding after removing the pulp and placed dry cotton for 5 minutes; teeth which will show physiologic mobility or exfoliated in 6 or 12 months follow up.

Age

From **5 years** old to **8 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Islamic Azad University Khorasgan Branch

Street address

University BLVD, Arghavanie, East jey street, Esfahan

City

Esfahan

Postal code**Approval date**

2012-11-06, 1391/08/16

Ethics committee reference number

91020909312

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

pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

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

Internal resorption

Timepoint

6 months after the intervention, and 12 months after intervention

Method of measurement

radiography

2**Description**

dental abscess and fistula

Timepoint

6 months after the intervention, and 12 months after intervention

Method of measurement

clinical examination

3**Description**

periapical radiolucency

Timepoint

6 months after the intervention, and 12 months after intervention

Method of measurement

radiography

4**Description**

pain

Timepoint

6 months after the intervention, and 12 months after intervention

Method of measurement

clinical examination and questions

Secondary outcomes**1****Description**

external resorption

Timepoint

Baseline, 6 months after the intervention, and 12 months after intervention

Method of measurement

radiography

2

Description

furcal radiolucency

Timepoint

6 months after the intervention, and 12 months after intervention

Method of measurement

radiography

Intervention groups

1

Description

intervention group: after pulpotomy, sodium hypochlorite is placed into the pulp chamber as the drug for 30 second

Category

Treatment - Drugs

2

Description

Control Group: after pulpotomy, ferric sulfate is placed into the pulp chamber as the drug for 15 second.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University Khorasgan Branch, Dental School, Department of Pediatric Dentistry

Full name of responsible person

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2

Recruitment center

Name of recruitment center

khanevadeh Special Dental Clinic

Full name of responsible person

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Street address

Baharestan Hospital, Sofeh Ave., Esfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University khorasgan Branch

Full name of responsible person

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Street address

No:27, 8th street, koye sepahan, Esfahan, Iran

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Esfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University khorasgan Branch

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty