Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of clinical and radiographic success of pulpotomy in primary molars restored with glass ionomer- crown: A double-blind randomized clinical trial

Protocol summary

Summary

Stainless steel crowns (SSCs) are treatment of choice subsequent to pulpotomy of primary molars. Despite durability of SSCs, due to prefabricated entity of crowns and their lack of accuracy at the margins, they cannot provide adequate seal. The aim of present study is to evaluate the clinical and radiographic success rate of pulpotomy in primary molars restored with glass ionomer- crown. In this double-blind randomized clinical trial, 55 children between 4-8 years old will participate. Inclusion criteria are requiring pulpotomy of mandibular primary second molars, complete physical and mental health, located in the positive or definitely positive classification of Frankle during pretreatment behavioral assessment, existence of enough crown tissue to repair, having nearly the same crown destruction on both sides. Any known allergy to medication or anesthetic solution and any emergency situation or tooth pain with pulp-origin are considered as exclusion criteria. Slit mouth design will be used in this study, in a way that each child will operate as a self-control and they will be randomly assigned, by the toss of a coin, to receive either crown restoration using crown-only or glass-ionomer crown. The time interval between two visits will be a week. In the second session, the child will receive the restoration not previously used. Pulpotomy and crown restoration of each tooth will be performed in a single session by one experienced pedodontist. Clinical and radiographic success will be recorded for each tooth at 6 months postoperatively according to criteria defined for successful clinical and radiographic treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609226105N6**

Registration date: **2016-11-14, 1395/08/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-11-14, 1395/08/24

Registrant information

Name

Nahid Ramazani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Zahedan University of Medical Sciences

Expected recruitment start date

2016-12-29, 1395/10/09

Expected recruitment end date

2017-03-25, 1396/01/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clinical and radiographic success of pulpotomy in primary molars restored with glass

ionomer- crown: A double-blind randomized clinical trial

Public title
Clinical and radiographic success of pulpotomy in primary molars restored with glass ionomer- crown
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria :Children between 4-8 years old, require pulpotomy in the primary mandibular second molars, having complete physical and mental health, located in the positive or definitely positive classification of Frankle during behavioral pretreatment assessment, existence of enough crown tissue to repair, nearly the same crown destruction on molars of both sides . Exclusion criteria :Any known allergy to medication or anesthetic solution, any emergency situation or tooth pain with pulp-origin .
Age
From **4 years** old to **8 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **55**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Science
Street address
Zahedan, Persian Gulf Blvd., College, resistance Research and Technology
City
Zahedan
Postal code
9816743463
Approval date
2016-07-31, 1395/05/10
Ethics committee reference number
IR.ZAUMS.REC.1395.41

Health conditions studied

1

Description of health condition studied
Dental Caries
ICD-10 code
B99-B99
ICD-10 code description
Other and unspecified infectious diseases

Primary outcomes

1

Description
clinical success
Timepoint
6 months after intervention 1 and 2
Method of measurement
using described criteria of successful clinical treatment including no swelling, tenderness to percussion, tenderness to palpation, mobility, fistula and abscess.

Secondary outcomes

1

Description
radiographic success
Timepoint
6 months after intervention 1 and 2
Method of measurement
using described criteria of successful radiographic treatment including no PDL widening, loss of lamina dura, radiolucency of furcation, internal or external root resorption, supporting bone destruction, pre apical radiolucency

Intervention groups

1

Description
Intervention 1 Applying topical anesthesia gel (TOPEX, Sultan Healthcare IND. CO, USA) for 60 seconds, administration mandibular block anesthesia by delivering 1 mL of lidocaine 2% with epinephrine 1:80000 (Psocaine-E, Darou Pakhsh IND. CO Iran) within 1.5 minutes, rubber dam isolation, caries removal, access cavity preparation with high speed hand piece using water spray, coronal pulp excision using a sharp spoon excavator, rinsing with 5 mL normal saline (Darou Pakhsh IND. CO, Iran) bleeding control and establishing hemostasis with light pressure applying by cotton pellet for 5 minutes, fixing pulp stumps with 1/5 dilution Buckley formocrezole solution (Buckley’s FormoCresol® SultanHealthcare, Hackensack, NJ) for 1 minutes, placing fast setting zinc oxide eugenole (Zoliran, Golchadent CO, Iran) a pulp dressing material, restoring tooth crown at the same appointment by stainless steel crown (3M/

ESPE. St. Paul MN, USA) using luting glass ionomer cement (GC America, Inc., Alsip, IL, USA).

Category

Other

2

Description

مداخله 2 اعمال ژل بي حسي موضعي (TOPEX, Sultan Healthcare IND. CO, USA) به مدت 60 ثانيه، انجام بي حسي بلوک مندیبل با تزریق 1 میلي ليتر از محلول ليدوکائين 2% با اپي نفرين 80000/1 (Persocaine-E, Darou Pakhsh IND. CO, Iran) طي زمان 5/1 دقيقه، ايزولاسيون با رابردم، حذف پوسيدگی، تهيه حفره دسترسی با توربين با سرعت بالا و اسپری آب، قطع پالپ تاجی با اکسکاواتور قاشقی تيز، شستشو با 5 ميلی ليتر نرمال سالين (Darou Pakhsh IND. CO, Iran)،کنترل خونريزی و ايجاد هموستاز با فشار ملايم گلوله پنبه به مدت 5 دقيقه، فيکس کردن پالپ ناحيه اريفيس با محلول فرموکرزول باکلی (Buckley’s FormoCresol® SultanHealthcare, Hackensack, NJ) با رقت يک پنجم به مدت 1 دقيقه، قرار دادن سمان زينک اکساید اوژنول زود سخت شونده بعنوان ماده پوشاننده پالپ، (Zoliran, Golchadent CO, Iran) ترميم تاج در همان جلسه با استفاده از گلاس آينومر ترميمی (GC America, Inc., Alsip, IL, USA) به عنوان ترميم بازسازی تاج، قرار دادن روکش استينلس استيل (3M/ ESPE. St. Paul MN, USA) با استفاده از سمان گلاس آينومر لوتينگ (GC America, Inc., Alsip, IL, USA)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Dental School

Full name of responsible person

Nahid Ramazani

Street address

Azadegan Avenue

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Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Zahedan University of Medical Sciences

Full name of responsible person

Hushang Rafighdoost

Street address

Daneshgah street, Zahedan

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9817699691

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research and Technology of Zahedan University of Medical Sciences

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

Zahedan University of Medical Sciences

Full name of responsible person

Nahid Ramazani

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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