

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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)

Phone

+98 54 1341 6706

Email address

ramazani77@zaums.ac.ir

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

(TOPEX, Sultan Healthcare IND. CO, USA) به مدت 60 ثانیه، انجام بی حسی بلوک مندیبل با تزریق 1 میلی لیتر از محلول لیدوکائین 2% با اپی (Persocaine-E, Darou Pakhsh IND. CO, Iran) نفرین 80000/1 طی زمان 5/1 دقیقه، ایزولاسیون با رابردم، حذف پوسیدگی، تهیه حفره دسترسی با توربین با سرعت بالا و اسپری آب، قطع پالپ تاجی با اکسکواتور قاشقی تیز، شستشو با 5 میلی لیتر نرمال سالین کنترل خونریزی و ایجاد هموستاز، (Darou Pakhsh IND. CO, Iran) با فشار ملایم گلوله پنبه به مدت 5 دقیقه، فیکس کردن پالپ ناحیه (Buckley's FormoCresol®) اریفیس با محلول فرموکروزول باکلی با رقت یک پنجم به مدت 1 (SultanHealthcare, Hackensack, NJ) دقیقه، قرار دادن سمان زینک اکساید اوژنول رود سخت شونده (Zoliran, Golchadent CO, Iran) بعنوان ماده پوشاننده پالپ، (GC America, Inc., Alsip, IL, USA) ترمیم تاج در همان جلسه با استفاده از گلاس آینومر ترمیمی به عنوان ترمیم بازسازی تاج، قرار (ESPE. St. Paul MN, USA) M/ دادن روکش استینلس استیل (3) با (GC America, Inc., Alsip, IL, USA) استفاده از سمان گلاس آینومر لوتینگ

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

City

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

City

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

Pediatrician / Associate Professor

Other areas of specialty/work

Street address

Azadegan avenue

City

9817699691

Postal code

9817699691

Phone

+98 54 3341 4005

Fax

Email

ramazani_nahid@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Dentistry

Full name of responsible person

Nahid Ramazani

Position

Associate Professor

Other areas of specialty/work

Street address

School of Dentistry, Department of Pediatrics

City

Zahedan

Postal code

9817699693

Phone

+98 54 3341 4005

Fax

Email

ramazani77@gmail.com

Web page address

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