

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of stainless steel and amalgam in restoration of pulpotomized primary molars

Protocol summary

Summary

Introduction and background: Pulpotomy is the most common pulp treatment in primary teeth. Final restoration of pulpotomized primary molar can have an effect on the failure of the endodontic treatment. The aim of this study was to compare the success rate of formocresol pulpotomy in primary molars restored with stainless steel crowns with those restored with amalgam. Design: this study was done as randomized clinical trial. Setting and conduct: 110 primary molars that met inclusion criteria pulpotomized with a conventional technique were randomly divided into 2 groups. In the amalgam group teeth were restored with amalgam and in SCC group teeth were restored with Stainless Steel Crown. Participants: 110 primary molars in children who were 4-7 years old. Inclusion criteria: the children who were healthy and did not have any contraindication for pulpotomy and did not have clinical and radiographic signs of radicular inflammation. Exclusion criteria: the children who were not healthy and those for whom pulpotomy was contraindicated and had clinical and radiographic signs of radicular inflammation. Intervention: After pulpotomy the teeth in SCC group were restored with SCC (3M ESPE U.S.A), and the teeth in amalgam group were restored with amalgam (Sinalux plus Sh. Dr. Faghihi Dental Co). Clinical and radiographic success was evaluated after 6, 12, and 24 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903023316N5**
Registration date: **2011-01-01, 1389/10/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-01, 1389/10/11

Registrant information

Name

Roza Haghgoo

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 6227

Email address

haghgoo@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research center- Shahed University- Dental School

Expected recruitment start date

2006-04-22, 1385/02/02

Expected recruitment end date

2008-07-23, 1387/05/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of stainless steel and amalgam in restoration of pulpotomized primary molars

Public title

Different types of restoration of pulpotomized primary molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the children who were healthy and did

not have any contraindication for pulpotomy and did not have clinical and radiographic signs of radicular inflammation. Exclusion criteria: the children who were not healthy and those for whom pulpotomy was contraindicated and had clinical and radiographic signs of radicular inflammation

Age

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

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **110**

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

Ethics committee of research center - Shahed University

Street address

Research center- between Forsat and Nosrat- Kargar Str

City

Tehran

Postal code

Approval date

2006-04-08, 1385/01/19

Ethics committee reference number

46/2-2054

Health conditions studied

1

Description of health condition studied

Pulpotomized primary molars

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Pain- Swelling- Mobility- Sensitivity to percussion- Internal resorption- External resorption- Furcal radiolucency

Timepoint

6months- 12 months-24months

Method of measurement

Explorer- Mirror- Radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Teeth restored by stainless steel crown (3M ESPE U.S.A)

Category

Treatment - Devices

2

Description

Control group: Teeth restored by amalgam(Sinalux, Sh Dr Faghihi, Dental Co)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dept of Pediatric Dentistry- Dental School- Shahed University

Full name of responsible person

Kalantary

Street address

N71- Italia Str- Vesal Ave

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research center, Shahed University, Dental School

Full name of responsible person

Dr Mohammad Bagher Rezvani

Street address

Between Forsat Str and Nosrat Str- Kargar Ave

City

Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Research center, Shahed University, Dental School
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
 Research center- Dental School- Shahed University
Full name of responsible person
 Mr Vafanoosh
Position
 MSC
Other areas of specialty/work
Street address
 Committee of Research center- Between Forsat Str and Nosrat Str- Kargar Ave
City
 Tehran
Postal code
Phone
 +98 21 6641 9664
Fax
Email
 sdntrc@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
 Research center- Dental School- Shahed University
Full name of responsible person
 Dr Mohammad Bagher Rezvani
Position
 Head of center / Assistant Prof

Other areas of specialty/work
Street address
 Dept of Operative Dentistry, Dental School, Shahed University
City
 Tehran
Postal code
Phone
 +98 21 8895 6227
Fax
Email
 mbrezvani@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
 Dental School Research Center, Shahed university
Full name of responsible person
 Dr Mohammad Bagher Rezvani
Position
 Head of center- Assistant Prof
Other areas of specialty/work
Street address
 Dept of Operative Dentistry- Dental School- Shahed University
City
 Tehran
Postal code
Phone
 +98 21 8895 6227
Fax
Email
Web page address

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