

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative invivo evaluation of different reconstruction techniques for severely destroyed primary anterior teeth.

Protocol summary

Summary

Purpose: This study compared the clinical success rates of a new reversed metal post technique and 2 conventional methods for restoration of maxillary primary incisors with extensive carious lesions. Methods: A total of 161 pulpectomized, severely decayed maxillary primary teeth, in 54 2- to 4-year-old patients presenting with early childhood caries, were randomly treated with 3 different restorative techniques: 53 composite post restorations, 54 fiber post restorations, and 54 reversed post restorations. Single-blind evaluations were made, according to the World Dental Federation criteria, at 3-, 6-, 9-, and 12-month intervals. Data were analyzed using nonparametric tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102105801N1**

Registration date: **2011-04-24, 1390/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-24, 1390/02/04

Registrant information

Name

Raha Kowsari Isfahan

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, school of dentistry

Expected recruitment start date

2010-05-22, 1389/03/01

Expected recruitment end date

2010-07-23, 1389/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative invivo evaluation of different reconstruction techniques for severely destroyed primary anterior teeth.

Public title

Comparison of different techniques for primary anterior teeth reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Child with no medical or mental disorder. 2- Primary anterior teeth with early childhood caries (ECC) or fracture due to trauma involving 3/4 of the crown. 3- Sound root structure and no caries of the root dentin, with sufficient amount of root structure present (1/3 external root resorption maximally). 4- No mobility. 5- No gingival recession/ gingivitis/ sinus tract 6- No trauma from occlusion as in crossbite, deepbite, etc. 7- No hypoplasia of teeth. 8- No deleterious oral habits.

Age

From **2 years** old to **4 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **161**

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
Isfahan University of Medical Sciences

Street address
Faculty of dentistry, Isfahan University of Medical Sciences, Hezarjarib Street

City
Isfahan

Postal code
8174673461

Approval date
2010-06-20, 1389/03/30

Ethics committee reference number
389337

Health conditions studied

1

Description of health condition studied
dental caries

ICD-10 code
K02

ICD-10 code description
Dental caries

Primary outcomes

1

Description
Restoration fracture

Timepoint
3 months after intervention up to one year

Method of measurement

FDI criteria

2

Description
Tooth fracture

Timepoint
3 months after intervention up to one year

Method of measurement
FDI criteria

3

Description
Marginal discoloration

Timepoint
3 months after intervention up to one year

Method of measurement
FDI criteria

4

Description
Restoration retention

Timepoint
3 months after intervention up to one year

Method of measurement
FDI criteria

5

Description
Color match

Timepoint
3 months after intervention up to one year

Method of measurement
FDI criteria

Secondary outcomes

empty

Intervention groups

1

Description
Group 1: 53 composite post

Category
Treatment - Other

2

Description
Group 2: 54 fiber post

Category
Treatment - Other

3

Description
Group 3: 54 reverse prefabricated metal post

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dental school, Isfahan University of Medical Sciences

Full name of responsible person**Street address****City**

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Dental school, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Abbasali Khademi

Street address

Hezar jarib Street

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Dental school, Isfahan 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**

Dental school, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Raha Kowsari Isfahan

Position

Resident of pediatric dentistry

Other areas of specialty/work**Street address**

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Isfahan University of Medical Sciences

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Dr. Alireza Eshghi

Position

MS of pedodontics, associated professor of dental faculty, Isfahan University of Medical Sciences

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Position

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Other areas of specialty/work**Street address**

Pediatric dentistry department, dental school, Isfahan University of Medical Sciences, Hezarjarib Street

City

Isfahan

Postal code**Phone****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