

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Evaluation of color restoration on child lifestyle and comparison of clinical and radiographical of the composite restoration with stainless steel crown in restoration of multi-surface caries in primary molar teeth

Protocol summary

Study aim

Evaluation of color restoration on child lifestyle and comparison of clinical and radiographical of the composite restoration with stainless steel crown in restoration of multi-surface caries in primary molar teeth

Design

Clinical trial with two intervention groups, with factorial groups, double-blind, randomized on 44 patients

Settings and conduct

This study is performed in the specialized department of Kerman Dental School. A total of 44 teeth are selected in children who meet the entry and exit criteria. Children are randomly divided into the following two groups based on even and odd numbers: the first group: tooth restoration with ssc (control group) and the second group: tooth restoration with composite (study group). At the end of the restoration session, a checklist to assess the parents and child's views on the appearance and color of the restoration is asked and completed immediately after viewing it. The clinical and radiographic success rate of tooth restoration is evaluated at intervals of 3, 6 and 12 months, and in these 3 follow-up sessions, a checklist related to the views of the child and parents regarding the importance of tooth appearance and color and its impact on the child's daily life is completed. .

Participants/Inclusion and exclusion criteria

Inclusion criteria include: 1- Physical and mental health, 2- Age 4 to 6 years, 3- Frankl cooperation level 3 or 4, 4- No history of dental restoration treatment, 5- Having at least one deciduous tooth Exclusion criteria included: 1- Lack of general health, 2- Lack of cooperation for treatment, 3- Having a history of deciduous molars restoration, 4- nonVital deciduous teeth, and 5- Tooth crowns were irreparable.

Intervention groups

Composite restoration and stainless steel crown

restoration

Main outcome variables

Success rate of composite and ssc restoration; the effect of restoration color on the quality of life of the child

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200831048565N1**

Registration date: **2020-09-21, 1399/06/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-21, 1399/06/31**

Update count: **0**

Registration date

2020-09-21, 1399/06/31

Registrant information

Name

Fateme Moslemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 9021

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-19, 1397/11/30

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of color restoration on child lifestyle and comparison of clinical and radiographical of the composite restoration with stainless steel crown in restoration of multi-surface caries in primary molar teeth

Public title
Evaluation of color restoration on child lifestyle and comparison of clinical and radiographical of the composite restoration with stainless steel crown in restoration of multi-surface caries in primary molar teeth

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
1- Physical and mental health 2- Age 4 to 6 years old 3- Frankl 3 or 4 level of cooperation 4- No history of dental restoration treatment 5- Having at least one deciduous molars with these conditions: a) According to radiography and signs and symptoms Clinical dental clinics. b) The teeth had caries of equal size and multilevel.
Exclusion criteria:
1- Lack of general health 2- Lack of cooperation for treatment 3- Having a history of restoration of deciduous molar teeth 4- Nonvital deciduous molar teeth 5- Tooth crowns were irreparable

Age
From **4 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling is simple randomization (coin tossing) and people are divided into two groups using coin tossing method. If after throwing it was on the coin line, the person is in the first group (tooth restoration with ssc) and if it was on the coin valve in the second group (tooth restoration with composite) and the coin is thrown until the specified sample volume is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The data were provided anonymously and in coded groups to the researcher, outcome assessor, data

analyzer, and data monitoring committee.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of kerman university of medical sciences

Street address

Kerman dental school,Shafa Ave ,Jomhoori Blvd.Kerman

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Province

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7818759689

Approval date

2020-02-16, 1398/11/27

Ethics committee reference number

IR.KMU.REC.1398.618

Health conditions studied

1

Description of health condition studied

dental caries

ICD-10 code

K02.9

ICD-10 code description

Dental caries, unspecified

Primary outcomes

1

Description

The effect of color restoration on the quality of daily life of the child

Timepoint

Immediately after repair, 3 months, 6 months, 12 months

Method of measurement

Designed questionnaire

2

Description

Success rate of composite restoration and SSC

Timepoint

Immediately after repair, 3 months, 6 months, 12 months

Method of measurement

Clinical and radiographic examination

Secondary outcomes

empty

Intervention groups**1****Description**

SSC restoration (control group): - Occlusion check - Separation of adjacent teeth with wooden wedge (enamel, Iran) - Proximal surfaces are cut with strile turbine bur (Tizkavan, Tehran, Iran) with rapid rotation and water spray. Contact with adjacent teeth was cut. - Cutting the cusps and occlusal surface was done using a strile turbine bur machine (Tizkavan, Tehran, Iran) with a high speed and water spray. A distance of 1 mm was created with the opposite tooth. - Any sharpness was removed using a strile turbine bur machine (Tizkavan, Tehran, Iran). Contour and crimp as needed. - SSC with glass ionomer (GC-Fuji I) was cemented.

Category

Treatment - Other

2**Description**

Occlusion check - complete removal of caries and removal of unsupported enamel using strile turbine fissure bur (Tizkavan, Tehran, Iran) using water spray. - Application of a layer of optical glass ionomer cement with a thickness of 1 mm on the base Reinforced eugenol zinc oxide (Kemdent, England) was placed to prevent interference of eugenol with the resin polymerization reaction and then cured by a calibrated light curing device for 40 seconds. Adapting the brace to the tooth and placing the wedge (Mina, Iran) to accurately match the brace to the tooth and holding the brace in place - the cavity was etched for 37 seconds using 37% phosphoric acid gel (Kimia, Iran). The acid was then washed with water powder. The enamel part of the cavity was dried with air powder and the dentin part of the cavity was dried with a cotton ball. It was then cured by a calibrated light curing machine for 20 seconds. - Flow composite (VOCO-X-tra base, USA) was placed in layers with a maximum thickness of 4 mm at the bottom of the cavity and each layer for at least 40 seconds. It was cured using a calibrated light curing device. -A composite layer (VOCO-X-TRF FILL, USA) with a maximum thickness of 4 mm was placed on the occlusal surface and cured for at least 40 seconds using a calibrated light curing device. -Occlusion after removing the tail rubber with The use of an articulation paper was checked and, if necessary, adjusted with a polishing bur (American Sharpener).

Category

Treatment - Other

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

kerman medical science univercity

Full name of responsible person

Raziyeh Shojaeipour

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

Kerman University of Medical Sciences

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Grant name

Oral and Dental Diseases Research Center, Kerman University of Medical Science, Kerman, Iran

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Raziyeh Shojaeipour

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available