

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of clinical durability of stainless steel crowns cemented with glass ionomer cement and Protooth silicate cement in primary molar teeth

Protocol summary

Study aim

In this in-vivo study we aim to use this cement for luting SSCs and compare clinical survival of the crowns cemented with novel Protooth cement and glass ionomer cement.

Design

This study is designed as a split-mouth and the teeth will be intervened bilaterally in one person (SSC will be cemented in the right quadrant teeth with glass ionomer cement and in the left quadrant teeth with the new protooth cement, regardless of the condition of the teeth and the degree of destruction). In this study, the groups are parallel and the sample size of 50 teeth will be randomly divided into two groups of 25 teeth. This study will be double blind.

Settings and conduct

In this study, all teeth will be restored by a post-graduate student of pediatric dentistry. Teeth with extensive proximal and/or occlusal caries and root-treated teeth will be selected. Crowns will be evaluated 6 months after cementation. In the follow-up session, clinical examination and intraoral camera observation of each crown will be done independently by two pediatric dental specialists, without knowing the type of cement.

Participants/Inclusion and exclusion criteria

Children with extensive caries in primary molars requiring restoration with stainless steel crowns (SSC).

Intervention groups

This study is designed as a split-mouth and the teeth will be intervened bilaterally in one person (SSC will be cemented in the right quadrant teeth with glass ionomer cement and in the left quadrant teeth with the new protooth cement, regardless of the condition of the teeth and the degree of destruction).

Main outcome variables

Check of SSC's mobility Recording the clinical views of SSCs using an intraoral camera and examining occlusal

wear and perforation of SSC Investigating the Crown's loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161227031608N3**

Registration date: **2023-10-30, 1402/08/08**

Registration timing: **prospective**

Last update: **2023-10-30, 1402/08/08**

Update count: **0**

Registration date

2023-10-30, 1402/08/08

Registrant information

Name

Ali Vafaei

Name of organization / entity

Tabriz medical sciences university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clinical durability of stainless steel crowns cemented with glass ionomer cement and Protooth silicate cement in primary molar teeth

Public title

Evaluation of clinical durability of stainless steel crowns cemented with glass ionomer cement and Protooth silicate cement in primary molar teeth

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children aged 2 to 12 years old Children with extensive caries in primary molars requiring restoration with stainless steel crowns (SSC).

Exclusion criteria:

Children who have less than two decayed teeth in their oral cavity

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **25**

More than 1 sample in each individual

Number of samples in each individual: **2**

In each person, SSC will be cemented in the teeth involved in the right quadrant with glass ionomer cement and in the teeth involved in the left quadrant with Protooth cement.

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The patient and the specialists who are responsible for checking the crowns in certain time intervals will not know about the type of cement, and the reviewers will only collect information about the durability of the crown.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht st., Tabriz University of Medical Sciences, Faculty of Dentistry, Pediatric dentistry department

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Tabriz

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East Azarbaijan

Postal code

5166614711

Approval date

2023-02-19, 1401/11/30

Ethics committee reference number

IR.TBZMED.REC.1401.1043

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**

SSC mobility (yes/no)

Timepoint

6 months

Method of measurement

Spoon excavator

2**Description**

SSC wear (yes/no)

Timepoint

6 months

Method of measurement

Clinical examination

3**Description**

SSC perforation (yes/no)

Timepoint

6 months

Method of measurement

Clinical examination

4

Description

loss of SSC (Yes/No)

Timepoint

6 months

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: SSC cemented with Protooth (Ultrafast Protooth cement, Dentosolve, Aarhus, Denmark). The material is mixed with the right consistency and two-thirds of the SSC is filled with cement. After drying the tooth under suitable isolation conditions, the crown is placed on the tooth and the cement additions are removed.

Category

Treatment - Other

2

Description

Control group: SSC cemented with Glass ionomer (Meron, VOCCO, Germany). The material is mixed with the right consistency and two-thirds of the SSC is filled with cement. After drying the tooth under suitable isolation conditions, the crown is placed on the tooth and the cement additions are removed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz dental faculty

Full name of responsible person

Amir Reza Jamei Khosroshahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ali Vafaei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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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