

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of pulpal response of primary teeth after direct pulp capping with Bioactive Glass and Mineral Trioxide Aggregate

Protocol summary

Summary

Abstract Objectives: The aim of this study was to evaluate pulpal response of primary teeth after direct pulp capping with two biocompatible materials, Mineral Trioxide Aggregate (MTA) and Bio Active Glass (BAG)

Design: This study will perform as double blind randomized clinical trial on 22 healthy primary canines which will be extracted for orthodontic reasons. Setting and conduct: The teeth will randomly divide into two groups by using a random-numbers table each with 11 teeth and will treat with direct pulp capping. Major Inclusion and Exclusion criteria: sound primary canines in children 7 to 8 years old that require extraction for orthodontic treatment; No more than one-third of the root resorption. Intervention: the exposure sites will randomly cap with MTA or BAG in the two groups. Main outcome measures: After 2 months the teeth will be extracted and will be evaluated the inflammation, dentine bridge formation, internal resorption and abscess histologically.

General information

Acronym

MTA,BAG

IRCT registration information

IRCT registration number: **IRCT2015100624397N1**

Registration date: **2015-11-23, 1394/09/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-23, 1394/09/02

Registrant information

Name

Motahare Ahmadvand

Name of organization / entity

Shahed university, Dental school,department of pediatric dentistry

Country

Iran (Islamic Republic of)

Phone

+98 21 8837 8039

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2011-09-25, 1390/07/03

Expected recruitment end date

2012-01-20, 1390/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of pulpal response of primary teeth after direct pulp capping with Bioactive Glass and Mineral Trioxide Aggregate

Public title

Clinical trial comparing the effects of Bioactive Glass and Mineral Trioxide Aggregate on pulpal response in children 7 to 8 years old

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: sound primary canines in children 7 to 8 years old that require extraction for orthodontic treatment. Exclusion criteria: primary canines that have root resorption more than the apical third.

Age

From **7 years** old to **8 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization by random-numbers table

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed university,dental school

Street address

Number 39, Italy St, Vesal St, Enghelab St

City

Tehran

Postal code

1417755351

Approval date

2011-05-14, 1390/02/24

Ethics committee reference number

40/104951

Health conditions studied

1

Description of health condition studied

direct pulp cap

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

inflammation

Timepoint

2 months after intervention

Method of measurement

Histologically

2

Description

dentinal bridge formation

Timepoint

2 months after intervention

Method of measurement

Histologically

3

Description

internal resorption

Timepoint

2 months after intervention

Method of measurement

Histologically

4

Description

abscess

Timepoint

2 months after intervention

Method of measurement

Histologically

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Control group: none

Category

Treatment - Other

2

Description

Intervention group1: Direct pulp capping in exposure site with MTA (Angelus, Brazil)

Category

Treatment - Other

3

Description

Intervention group 2: Direct pulp capping in exposure site with BAG (3iImplant Innovations, USA)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahed university, faculty of dentistry

Full name of responsible person

Karami

Street address

Number 39, Italy St, Vesal St, Enghelab St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of dental school of Shahed university

Full name of responsible person

Gharaje

Street address

Number 39, Italy St, Vesal St, Enghelab St

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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

Vice Chancellor for research of dental school of Shahed university

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

Shahed university, Faculty of dentistry

Full name of responsible person

Roza Haghgoo

Position

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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