Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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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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Tehran
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
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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