Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A comparative study of clinical and radiographic success rates of BMP2 and MTA in pulpotomy of primary molars in 3 to 6 year old children

Protocol summary

Summary

The purpose of this study is to evaluate clinical and radiographic success and failure rate of MTA and BMP2 in pulpotomy of primary molars in 12 months follow up. This study is a randomazed single blinde study and is in stage 3 of clinical trial. In this study 3 to 6 year old children with at least two mandibular primary molars need pulpotomy, is studied. A total of 50 teeth are selected. The criteria for selection of teeth are: exposed vital tooth without signs and symptoms and with no clinical or radiographic evidence of pulp degeneration and the possibility of proper restoration of the tooth. Teeth with any sign and symptom and clinical or radiographic evidence of pulp degeneration, physiologic mobility and any pathologic root resorption are excluded from the study. The teeth divided into two equal groups. For all teeth caries are removed and coronal access is completed. After coronal pulp amputation, in one group MTA is used as a pulp dressing agent and in the other group BMP2 is used with gel foam. The teeth are restored with Interim Restorative Material (IRM) and then stainless steel crown is placed. Children are recalled for clinical and radiographic evaluation every 3 months for a total follow up period of one year. The case is regarded as a failure when one or more of the following signs are present: internal and external resorption, radiolucency, widening of periodontal ligament, pain, swelling, sensitive to percussion, pathologic mobility or sinus tract.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017062434726N1**
Registration date: **2017-08-31, 1396/06/09**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-08-31, 1396/06/09

Registrant information

Name

Nosrat Nourbakhsh

Name of organization / entity

School of dentistry, Esfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Dental school, Esfahan University of Medical Sciences; Kowsar Kohangen Company

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of clinical and radiographic success rates of BMP2 and MTA in pulpotomy of primary molars in 3 to 6 year old children

Public title

Effect of BMP2 versus MTA as a medicament in pulpotomy of primary molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Exposed vital tooth without signs and symptoms; Teeth with no clinical or radiographic evidence of pulp degeneration; The possibility of proper restoration of the tooth. Exclusion criteria: Teeth with signs and symptoms; Clinical or radiographic evidence of pulp degeneration; physiologic mobility; Evidence of any pathologial root resorption.

Age

From **3 years** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The Split mouth design is applied in this study. Base on block randomization table all of the participants will be assigned to receive pulpotomy therapy with MTA in primary mandibular molars of one side and pulpotomy with BMP2 in primary mandibular molars of another side.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Esfahan University of Medical Sciences

Street address

Ethics committe, Dental school, Esfahan University of Medical Sciences, Hezarjerib street, Esfahan

City

Esfahan

Postal code

Approval date

2016-05-27, 1395/03/07

Ethics committee reference number

IR.MUI.REC.1395.3.753

Health conditions studied

1

Description of health condition studied

reversible pulpitis

ICD-10 code

k04.0

ICD-10 code description

reversible pulpitis

Primary outcomes

1

Description

pain

Timepoint

before intervention, 3 months, 6months, 9months and 12 months after intervention

Method of measurement

clinical examination

2

Description

sensitive to percussion

Timepoint

before intervention, 3 months, 6months, 9months and 12 months after intervention

Method of measurement

clinical examination

3

Description

swelling

Timepoint

before intervention, 3 months, 6months, 9months and 12 months after intervention

Method of measurement

clinical examination

4

Description

sinus tract

Timepoint

before intervention, 3 months, 6months, 9months and 12 months after intervention

Method of measurement

clinical examination

5

Description

pathologic mobility

Timepoint

before intervention, 3 months, 6months, 9months and 12 months after intervention

Method of measurement

clinical examination

Secondary outcomes

1

Description
internal resorption
Timepoint
before intervention, 3months, 6months, 9months and 12months after intervention
Method of measurement
radigraphic examination

2

Description
external resorption
Timepoint
before intervention, 3months, 6months, 9months and 12months after intervention
Method of measurement
radigraphic examination

3

Description
PDL widening
Timepoint
before intervention, 3months, 6months, 9months and 12months after intervention
Method of measurement
radigraphic examination

4

Description
radiolucency
Timepoint
before intervention, 3months, 6months, 9months and 12months after intervention
Method of measurement
radigraphic examination

Intervention groups

1

Description
Intervention group: After pulpotomy treatment, 1 microgram recombinant human bone morphogenetic protein 2 (rhBMP2) is placed in pulp chamber.
Category
Treatment - Other

2

Description
group2: After pulpotomy treatment, MTA paste is placed in pulp chamber as a standard pulpotomy medicament.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric Department, School of Dentistry,Esfahan University of Medical Sciences
Full name of responsible person
Dr. Nosrat Nourbakhsh
Street address
School of Dentistry, Esfahan University of Medical Sciences, Hezarjerib street, Esfahan
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Esfahan University of Medical Sciences
Full name of responsible person
Elham Sadat Binande
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Vice chancellor for research, Dental school, Esfahan University of Medical Sciences, Hezarjerib street, Esfahan
City
Esfahan
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, Esfahan University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Kowsar Kohan Gen company
Full name of responsible person
Amir Hossein Behnia
Street address
Flat. A13, Ghadir street

City
Sepahanshahr
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kowsar Kohan Gen company
Proportion provided by this source
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

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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