

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of Clinical and Radiographic outcomes of 3 different techniques of Miniature Pulpotomy in Primary second Molars in 4-7 year-old children

Protocol summary

Summary

purpose of the study: evaluate the clinical and radiographic success rate of Miniature pulpotomy with 3 different techniques in primary second mandibular molars Design: Randomized, Single Blind, without placebo, one center, Phase 3 Population: Inclusion Criteria : 4-7 year-old ; healthy and cooperative children ; with deep carious primary second molars Exclusion Criteria: spontaneous pain ; swelling ; tenderness ; sinus tract ; excessive bleeding from the exposure site ; pathologic mobility ; no exposure ; pathologic root resorption ; periapical or furcation bone radiolucency ; PDL widening ; physiologic root resorption more than 1/3 Sample Size: 63 mandibular primary second molars Intervention: In this trial, 63 mandibular primary second molars in 4-7 year-old children will randomly undergo Miniature pulpotomy with MTA, MTA-Low Level Diode Laser Therapy and MTA-High Level Diode Laser Therapy. Then restoration with stainless steel crowns(SSCs) will be done. Following the treatment, the teeth will monitor for clinical and radiographic evaluation after 6 and 12 months. Time:6 and 12 months follow-up Outcome:clinical and radiographic success or failure of treatment will define with observation and check list

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100524373N1**

Registration date: **2015-11-13, 1394/08/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-13, 1394/08/22

Registrant information

Name

Sima Changiz

Name of organization / entity

Mashhad University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences- Dental School
Grant of Responsible Party

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Clinical and Radiographic outcomes of 3 different techniques of Miniature Pulpotomy in Primary second Molars in 4-7 year-old children

Public title

Miniature pulpotomy with 3 different techniques in primary second molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 4-7 year-old ; healthy and cooperative children ; with deep carious primary second molars
Exclusion Criteria: spontaneous pain ;swelling ;
tenderness ; sinus tract ; excessive bleeding from the exposure site ; pathologic mobility ; no exposure ;
pathologic root resorption ; periapical or furcation bone radiolucency ; PDL widening ; physiologic root resorption more than 1/3

Age

From **4 years** old to **7 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Mashhad University of Medical Sciences

Street address

Park Square

City

Mashhad

Postal code**Approval date**

2015-02-18, 1393/11/29

Ethics committee reference number

930913

Health conditions studied**1****Description of health condition studied**

Pulpal Treatment in primary second molars

ICD-10 code

K04.9

ICD-10 code description

Other and unspecified diseases of pulp and periapical

tissues

Primary outcomes**1****Description**

successful outcome of treatment as indicated by clinical signs

Timepoint

up to 12 months

Method of measurement

with observation and check list

Secondary outcomes**1****Description**

successful radiographic outcome of treatment

Timepoint

up to 12 months

Method of measurement

with observation of radiography and check list

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

Miniature Pulpotomy of primary second molars with MTA

Category

Treatment - Other

2**Description**

Miniature Pulpotomy of primary second molars with Low Level Laser Therapy-MTA

Category

Treatment - Other

3**Description**

Miniature Pulpotomy of primary second molars with High Level Laser Therapy-MTA

Category

Treatment - Other

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

Dental School- Mashhad University of Medical Sciences

Full name of responsible person

Dr Masoumeh Ebrahimi- Dr Abbas Makarem

Street address

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Masoumeh Ebrahimi
Street address
Mellat Park Square
City
Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

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
Mashhad university of medical sciences
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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