

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison evaluation of Puls oximetry, Electrical Pulp test and Cold Test for assessing pulp vitality in permanent immature vital teeth, in 8-12 years old children

Protocol summary

Summary

This study aimed to compare pulse oximetry, electric pulp test and cold test in assessing pulp vitality of immature vital permanent teeth. Study design is observational. Patients aged 8-12 years old with immature vital maxillary central and lateral incisors are include in the study. Patients should have panoramic radiographs to determine the stage of root development. Otherwise are excluded. Additional radiographs will not take. the number of patients is 120 .pulp vitality will assess by puls oximeter, electrical pulp test and cold test. These 3 methods will compare in permanent immature vital teeth. No other intervention takes place and It is just a diagnostic study. Any re-evaluation will not performed at another interval.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022326723N1**

Registration date: **2016-04-16, 1395/01/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-16, 1395/01/28

Registrant information

Name

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Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Dental school, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison evaluation of Puls oximetry, Electrical Pulp test and Cold Test for assessing pulp vitality in permanent immature vital teeth, in 8-12 years old children

Public title

Comparison evaluation of Puls oximetry, Electrical Pulp test and Cold Test for assessing pulp vitality in permanent immature vital teeth

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: patients without systemic disease with healthy, immature permanent maxillary central and lateral teeth and a crown of clinically healthy without caries, fracture, discoloration and restoration; no history of trauma in the head and face and radiographs to determine root developmental stage Exclusion criteria:

developmental and structural defects in teeth to the presence of symptoms of pain and inflammation and periodontal disease.

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of medical Sciences

Street address

journal of dental school, 4th floor , dental school, Shahid Beheshti University of medical Sciences , Daneshjoo Blvd , Evin , shahid Chamran highway

City

Tehran

Postal code

1983963113

Approval date

2015-12-28, 1394/10/07

Ethics committee reference number

IR.SBMU.RIDS.REC.1394.107

Health conditions studied

1

Description of health condition studied

Pulp vitality of immature teeth

ICD-10 code

K04.9

ICD-10 code description

Other and unspecified diseases of pulp and periapical tissues

Primary outcomes

1

Description

Cold test

Timepoint

Before intervention

Method of measurement

Cold spray

2

Description

Electrical pulp test

Timepoint

Before intervention

Method of measurement

EPT device

Secondary outcomes

empty

Intervention groups

1

Description

pulp vitality

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Forough Akbari

Street address

Pediatric Department, Dental School, Shahid Beheshti University of medical Sciences, Daneshjoo Blvd., Evin, Shahid Chamran highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahrokh Amini

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4th floor, Dental School, Shahid Beheshti University of medical Sciences, Daneshjoo Blvd., Evin, Shahid Chamran highway

City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
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Full name of responsible person
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Position
Post graduate student of pediatric 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