Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparison of Success Rate of sodium hypochlorite and formocresol for Primary Molar Teeth Pulpotomy

Protocol summary

Summary

This study investigates whether sodium hypochlorite can alternative for Formocresol in pulpotomy of primary teeth.This randomized, double-blind, without control placebo,one central,stage one of clinical trial.30 children between four and nine years; healthy and cooperative each with at least two primary mandibular second molar requiring pulpotomy; were randomly allocated to two groups . All the teeth received stainless steel crown after conventional pulpotomy procedure with either sodium hypochlorite (applied for 15 second) or Formocresol (applied for 5 minute). Clinical and radiographic signs/symptoms recorded at six and 12 months.primary outcom: clinical success and secondary outcom: radiographic success

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015092717935N5**
Registration date: **2016-02-15, 1394/11/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-15, 1394/11/26

Registrant information

Name

Zahra Bahrololoomi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences-Yazd

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences of Yazd

Expected recruitment start date

2015-11-11, 1394/08/20

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Success Rate of sodium hypochlorite and formocresol for Primary Molar Teeth Pulpotomy

Public title

Comparison of Success Rate of two material in Primary Molar Teeth Pulpotomy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:primary molars with vital carious pulp exposures that bled upon entering the pulp chambers,no clinical symptoms or evidence of pulp degeneration, such as a history of spontaneous and nocturnal pain, pain on percussion, history of swelling, mobility, or sinus tracts,no radiographic signs of internal or pathologic external resorption and no furcation radiolucency,teeth would be restorable with posterior stainless steel crowns.exclusion criteria:uncooperative children.

Age

From **4 years** old to **9 years** old

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
tabel randomied numerics

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences
Street address
Faculty of Dentistry, Dahe Fajr Blvd, Yazd
City
Yazd
Postal code
-
Approval date
2015-11-03, 1394/08/12
Ethics committee reference number
IR.SSU.REC.1394.107

Health conditions studied

1

Description of health condition studied
pulpotomy
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
clinical Success Pulpotomy
Timepoint
6 and 12 mounts after Pulpotomy
Method of measurement
clinical examination

Secondary outcomes

1

Description
radiographic success Pulpotomy
Timepoint
6 and 12 mounts after Pulpotomy
Method of measurement
observation radiography

Intervention groups

1

Description
Experimental group:0/5% sodium hypochlorite;applied for 30second
Category
Other

2

Description
Control group: Formocresol;1:5 Buckley’s solution;applied for 5minute
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi University of Medical Sciences of Yazd
Full name of responsible person
Atefeh shakib
Street address
Faculty of Dentistry, Dahe Fajr Blvd, Yazd
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Shahid Sadoughi University of Medical Sciences of Yazd
Full name of responsible person
Dr. Fateme Ezoddini Ardakani
Street address
Faculty of Dentistry, Dahe Fajr Blvd, Yazd
City

Yazd

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 Shahid Sadoughi University of Medical Sciences of Yazd

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

Yazd Dentistry FAaculty University of Medical Sciences,

Full name of responsible person

Atefeh Shakib

Position

Postgraduate student of pediatric dentistry

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Person responsible for updating data

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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