Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Histological evaluation of the pulp of primary teeth after pulpotomy with formocresol and SUAB2

Protocol summary

Summary

Introduction and Background: Formocresol is a popular pulpotomy medicament in the primary dentition. Because of its systemic and local side effect, it may be essential to use another material instead of formocresol. Objectives: The purpose of this study was to assess the histological pulpal response after pulpotomy with two different agents: formocresol and SUAB2. Design: This study was a randomized clinical trial study. Setting and conduct: In this study pulpotomy was done with formocresol and SUAB2. Participants: 14 teeth of 7 children that must be extracted due to orthodontic treatment were selected. Inclusion criteria: children who were 7-8 years and otherwise healthy and had the canines that were sound and must be extracted due to orthodontic treatment Intervention: These teeth were divided randomly into 2 groups: formocresol and SUAB2. 7 teeth were pulpotomized with SUAB2 (a herbal prepration, 5 minutes, 1 time) and 7 teeth with formocresol (1.5, DENTSPLY/ a French company, 5 minutes, 1 time). These teeth were extracted after 2 months and pulpal response inflammation, abscess, internal resorption, fibrosis, necrosis, and dentinal bridge formation) was evaluated. Finally the data was analyzed using mann-withney and fisher exact tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901243316N4**
Registration date: **2010-12-30, 1389/10/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-12-30, 1389/10/09

Registrant information

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Recruitment status

Recruitment complete

Funding source

Research Center, Shahed university Dental School

Expected recruitment start date

2009-07-12, 1388/04/21

Expected recruitment end date

2010-04-20, 1389/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Histological evaluation of the pulp of primary teeth after pulpotomy with formocresol and SUAB2

Public title

Evaluation of pulp after pulpotomy with formocresol and SUAB2

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 14 teeth in children who were 7-8 years; Children who were healthy and had the canines that were sound and must be extracted due to orthodontic treatment. Exclusion criteria: Children who

were not healthy and did not have any canine tooth that must be extracted due to orthodontic treatment

Age

From **7 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University Research Center, Kargar St., between Forsat and Nosrat

City

Tehran

Postal code

Approval date

2009-07-01, 1388/04/10

Ethics committee reference number

41/629

Health conditions studied

1

Description of health condition studied

Pulp of primary teeth

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Inflammation- Fibrosis- Necrosis- Internal resorption-

Timepoint

2 months after intervention

Method of measurement

Horsted etal scale

Secondary outcomes

1

Description

Dentinal bridge formation

Timepoint

2 months

Method of measurement

Horsted etal

Intervention groups

1

Description

Pulpotomy with formocresol group: formocresol 1.5, DENTSPLY/a french company, 5 minutes, 1 time

Category

Treatment - Drugs

2

Description

Pulpotomy with SUAB2 group: herbal agent, 5 minutes, 1 time

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School, Shahed university

Full name of responsible person

Ms Kalantary

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research center- Shahed University

Full name of responsible person

Dr Rezvani

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Kargar St., Brtween Forsat and Nosrat

City
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research center- 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

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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