

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Histopathological evaluation of pulp after pulpotomy of primary teeth with Sodium hypochlorite and formocresol

#### Protocol summary

##### Summary

Background and Aim: Formocresol is one of the most common pulpotomy medicament in the primary teeth. Because of its systemic and local side effects, it may be essential to use another material instead of formocresol. The purpose of this study was to assess pulpal changes of the pulp of primary teeth after pulpotomy with Sodium hypochlorite and formocresol Methods and Materials: In this Randomized clinical trial, 22 teeth that must be extracted because of orthodontic treatment were selected. These teeth were divided randomly into 2 groups. 11 teeth were pulpotomized with formocresol and 11 teeth with Sodium hypochlorite. These teeth were extracted after 2 months and pulpal response was evaluated according to the degree of inflammation and extent of pulpal involvement. Dentinal bridge formation was also evaluated. Finally the data was analyzed with Mann Whitney test. Key words: Formocresol- Histological evaluation- Pulpotomy- Primary teeth- Sodium hypochlorite ted. These teeth were divided randomly into 2 groups. 11 teeth were pulpotomized with formocresol and 11 teeth with Sodium hypochlorite. These teeth were extracted after 2 months and pulpal response was evaluated according to the degree of inflammation and extent of pulpal involvement . Dentinal bridge formation was also evaluated. Finally the data was analyzed with mann withney test . Key words: Formocresol- Histological evaluation- Pulpotomy- Primary teeth- Sodium hypochlorite

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138901243316N3**

Registration date: **2010-05-30, 1389/03/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-05-30, 1389/03/09

##### Registrant information

###### Name

Roza Haghgoo

###### Name of organization / entity

Shahed University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8865 6227

###### Email address

haghgoo@shahed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research center of Dental School - Shahed University

##### Expected recruitment start date

2008-08-14, 1387/05/24

##### Expected recruitment end date

2009-02-20, 1387/12/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Histopathological evaluation of pulp after pulpotomy of primary teeth with Sodium hypochlorite and formocresol

##### Public title

Histopathological evaluation

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Primary canines that were healthy and must be extracted due to orthodontic treatment

Exclusion criteria: Root resorption more than one third

#### Age

From **7 years** old to **9 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **22**

#### 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

Ethics committee of Shahed University

###### Street address

Committee of research centers- Between Forsat Str and Nosrat Str- Kargar Ave

###### City

Tehran

###### Postal code

###### Approval date

empty

###### Ethics committee reference number

46/2-2199

### Health conditions studied

#### 1

##### Description of health condition studied

Response of pulp of primary teeth

##### ICD-10 code

-

##### ICD-10 code description

-

### Primary outcomes

#### 1

##### Description

inflammation and abscess and necrosis , internal resorption and bridge formation

##### Timepoint

2 months

##### Method of measurement

Horsted etal scale

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Pulpotomy with formocresol

##### Category

Treatment - Drugs

#### 2

##### Description

Pulpotomy with Sodium hypochlorite

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Dept of Pediatric Dentistry- Dental School- Shahed University

###### Full name of responsible person

Ms Kalantary

###### Street address

###### City

Tehran

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Research center - between Forsat Str and Nosrat Str- Kargar Ave

###### Full name of responsible person

Dr Rezvani

###### Street address

Between Forsat Str and Nosrat Str- Kargar Ave

###### City

Tehran

###### Grant name

###### Grant code / Reference number

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

Yes

**Title of funding source**

Research center - between Forsat Str and Nosrat Str- Kargar Ave

**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**

Research center- Dental School- Shahed University

**Full name of responsible person**

Mr Vafanoosh

**Position**

Master of Science

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**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*