

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### **Pilot Randomized Controlled Clinical Trial for Radiographic and Clinical Evaluation of Three Restorative Methods in Primary Molars with Multi-Surface Carious Lesions: Conventional Stainless Steel Crown, Triple-Modified Atraumatic Restorative Treatment, Hall Technique.**

#### **Protocol summary**

##### **Study aim**

comparing the results of three restorative techniques: stainless steel crown, atraumatic restorative treatment, Hall technique

##### **Design**

Groups: stainless steel crown, atraumatic restorative treatment, Hall technique Computer-generated Individualized block-randomization was performed. Operator was blind to type of treatment until the presence of each patient Treatment was performed parallel for groups

##### **Settings and conduct**

123 primary molars of patients (attending Mashhad faculty of dentistry) were randomly assigned to these groups: Group1(Conventional SSC) Group 2 (Hall technique) Group 3 (Modified ART) Recorded data: Duration of treatment,Pain and discomfort (child perception),Pain and anxiety ( dentist's perception),Parental satisfaction The patients were re-examined 6 months and 1 year later. Clinical and radiographic evaluations were performed and the following data was recorded:Clinical sign of major and minor failure of the treatment. Radiographic signs of major or minor failure of the treatment. Parents' satisfaction , changes in canine relationship. Data was analyzed using the Fisher's exact test and chi-square test.The standard value of statistically significant difference was  $p \leq 0.05$ .

##### **Participants/Inclusion and exclusion criteria**

good general health, past history of restorative treatments including local anesthesia, high risk of caries incidence according to Guideline (AAPD), Written and verbal informed consents obtained from parents or guardians, children 4 to 9-year-old children having at least one multi-surface carious lesion of primary molar, affecting at least one interproximal surface of the tooth

##### **Intervention groups**

stainless steel crown, atraumatic restorative treatment, Hall technique

##### **Main outcome variables**

treatment type Changes in inter-canine distance  
Duration of treatment Pain/discomfort (child perception)  
Pain/anxiety ( dentist's perception) Parental satisfaction

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20181226042138N1**  
Registration date: **2019-02-10, 1397/11/21**  
Registration timing: **retrospective**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

##### **Registration date**

2019-02-10, 1397/11/21

##### **Registrant information**

##### **Name**

Elham Afshari

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 17 3193 2160

##### **Email address**

dr.afshari@goums.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

**Expected recruitment start date**

2016-09-22, 1395/07/01

**Expected recruitment end date**

2017-03-20, 1395/12/30

**Actual recruitment start date**

2016-09-22, 1395/07/01

**Actual recruitment end date**

2017-06-10, 1396/03/20

**Trial completion date**

2018-06-10, 1397/03/20

**Scientific title**

Pilot Randomized Controlled Clinical Trial for Radiographic and Clinical Evaluation of Three Restorative Methods in Primary Molars with Multi-Surface Carious Lesions: Conventional Stainless Steel Crown, Triple-Modified Atraumatic Restorative Treatment, Hall Technique.

**Public title**

Comparing the Results of Three Restorative Methods in Primary Molars with Multi-Surface Carious Lesions: Conventional Stainless Steel Crown, Triple-Modified Atraumatic Restorative Treatment, Hall Technique.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

good general health, past history of restorative treatments which had included local anesthesia, high risk of caries incidence according to Guideline of American Academy of Pediatric Dentistry (AAPD) on Caries-risk Assessment Written and verbal informed consents obtained from parents or guardians of the children 4 to 9-year-old children having at least one multi-surface carious lesion of primary molar, affecting at least one interproximal surface of the tooth

**Exclusion criteria:**

Compromised health status. lack of informed consent of parent or patient. Medium or low risk of dental caries. Misalignment or desire for dental radiography

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

Actual sample size reached: **123**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Computer-generated Individualized block-randomization was performed. Operator was blind to type of treatment until the presence of each patient. The assistant informed the operator by that time.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Mashhad Faculty of Dentistry Committee for Ethics

**Street address**

Mashhad faculty of dentistry- Mellat park square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Approval date**

2016-02-24, 1394/12/05

**Ethics committee reference number**

IR.MUMS.sd.REC.1394.91

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

dental caries

**ICD-10 code**

K02.9

**ICD-10 code description**

Dental caries, unspecified

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

major or minor failure of treatment

**Timepoint**

6 months- 12 months

**Method of measurement**

radiographic and clinical evaluation

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

time spent on treatment

**Timepoint**

just after the treatment

**Method of measurement**

digital chronometer

## Intervention groups

### 1

#### Description

Intervention group: Hall technique

#### Category

Treatment - Other

### 2

#### Description

Intervention group: modified atraumatic restorative treatment

#### Category

Treatment - Other

### 3

#### Description

Control group: conventional stainless steel crown

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mashhad dental faculty

##### Full name of responsible person

Elham Afshari

##### Street address

Mashhad dental faculty, Mellat Park square

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948959

##### Phone

+98 51 3883 2301

##### Email

j.m.dental.s@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Alireza Sarrafshirazi

##### Street address

Mashhad faculty of dentistry, Mallat park square

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##### Province

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##### Postal code

9177948959

##### Phone

+98 51 3883 2301

##### Email

sarrafa@mums.ac.ir

#### 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

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Alireza Sarrafshirazi

##### Position

professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

##### Street address

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##### Province

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##### Postal code

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Alireza Sarrafshirazi

##### Position

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for updating data****Contact****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Elham Afshari

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

will be sent on demand of individual researchers

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available