Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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 squre
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 treatmnet
Method of measurement

digital choronometer

Intervention groups

1

Description
Intervention group: Hall technique
Category
Treatment - Other

2

Description
Intervention group: modified atraumatic restorative tretament
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
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9177948959
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+98 51 3883 2301
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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
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Mashhad faculty of dentistry, Mallat park square
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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
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Person responsible for updating data

Contact
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Gorgan University of Medical Sciences
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Assistant professor
Latest degree
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Dentistry
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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