Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative evaluation of the efficacy of calcium hydroxide with resin modified glass ionomer versus TheraCal in indirect pulp cap in teeth with deep caries: a clinical trial study

Protocol summary

Study aim
Determining the efficacy of TheraCal versus calcium hydroxide in indirect pulp cap

Design
A clinical trial with a control group, double blind, the number of 50 selected patients in two treatment groups with an equal number and randomization by permutation blocks using Allcation Random software.

Settings and conduct
This study will be a double-blind clinical trial (both for patients and statistical analysts) and will examine 50 patients referred to Shahrekord dental school and office. The patients will not know about the content of the received intervention and the statistical analyst will not know about the content of the information file that will be provided in the form of groups A and B. Patients will be randomly divided into two groups with equal numbers: Group A: treated with Calcium Hydroxide Self-Cure and Liner Hybrid Ionomer Light Cure and Group B: treated with TheraCal LC. Clinical examinations to check pain after treatment in the follow-up period of the patient in 21 days, three months and six months after treatment and if there are clinical symptoms, radiographic examination will be done to check periodontal ligament(PDL) space six months after treatment.

Participants/Inclusion and exclusion criteria
Patients referring to Shahrekord dental school and office - Criteria for entering the study 1. Patients with mature permanent teeth 2. Patients with caries in the dentin more than one-half or three-quarters of the thickness of the dentin 3. Patients with reversible pulpitis - Exclusion criteria 1. Patients with irreversible pulpitis 2. Tooth with necrotic pulp

Intervention groups
Group A: people treated with self-cure calcium hydroxide and light cure hybrid ionomer liner, and group B: people treated with TheraCal

Main outcome variables
pain level (clinical sensitivity) Pulp vitality PDL thickening

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231025059853N1**
Registration date: **2023-11-14, 1402/08/23**
Registration timing: **retrospective**

Last update: **2023-11-14, 1402/08/23**
Update count: **0**

Registration date
2023-11-14, 1402/08/23

Registrant information

Name
Shamim Mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3270 9327

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khorshid_mohammad@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-13, 1402/06/22

Expected recruitment end date
2023-11-13, 1402/08/22

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the efficacy of calcium hydroxide with resin modified glass ionomer versus TheraCal in indirect pulp cap in teeth with deep caries: a clinical trial study

Public title

Comparative evaluation of the efficacy of calcium hydroxide with resin modified glass ionomer versus TheraCal in indirect pulp cap: a clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with mature permanent teeth with closed apex Patients with caries in the dentin more than one-half or three-quarters of the thickness of the dentin Patients with reversible pulpitis Dental samples must respond positively to the cold test

Exclusion criteria:

Patients with irreversible pulpitis Teeth with internal and external absorption Tooth with periapical lesion Tooth with necrotic pulp Cracked teeth People with periodontitis

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method of replacement blocks will be used with the size of each block equal to 6. The randomization list will be prepared by the permutation block method using Allcation Random software and will be provided to the researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

This clinical trial study will be conducted in a double-blind manner so that both the patients participating in the study and the statistical analyst will be blinded. Blinding for the patients will be in such a way that theracal and calcium hydroxide materials have similar colors and the patients will not have any information about the content of the received intervention. Also, the information file will be provided to the statistical analyst in the form of group A and group B, and this person will not have any information about the content of the intervention of groups A and B, which will cause all the results to be analyzed based on groups A and B and will be provided to the main researcher.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Shahrekord University of Medical Sciences

Street address

Fadak complex,Hamedanian St.,East Haht Behesht St.

City

Isfahan

Province

Isfehan

Postal code

8157967764

Approval date

2023-09-13, 1402/06/22

Ethics committee reference number

IR.SKUMS.MED.REC.1402.048

Health conditions studied

1

Description of health condition studied

Indirect pulp capping for teeth with deep decay

ICD-10 code

K02.1

ICD-10 code description

Caries of dentine

Primary outcomes

1

Description

The degree of pain or clinical sensitivity

Timepoint

21 days, three months and six months after treatment

Method of measurement

Based on the Numeric Rating Scale

2

Description

Vitality of the pulp or Vitality of the dental nerve, which is determined by the feeling of cold or heat after

performing vitality tests

Timepoint

21 days, three months and six months after treatment

Method of measurement

Vitality tests (cold and heat test)

3

Description

Widening of the periodontal ligament space around the apex in radiographs

Timepoint

6 months after treatment in case of pain and clinical sensitivity

Method of measurement

Radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People treated with TheraCal : For both intervention and control groups, local anesthesia, isolation of the investigated tooth and selective removal of caries are performed. The tooth is disinfected with chlorhexidine 2% and rinsed with normal saline. Then the teeth are randomly divided into two groups: the intervention group consists of 25 teeth and will be treated with TheraCal LC (calcium silicate liner modified with light cure resin): the material is applied to the deepest points of the cavity floor and It is then light cured according to the manufacturer's instructions. TheraCal LC from Bisco is supplied by the manufacturer as a disposable syringe and syringe head and does not require preparation before use.

Category

Treatment - Other

2

Description

Control group: people treated with self cure calcium hydroxide (Dycal) and light cure hybrid ionomer liner: Dycal is available as a two-paste system (a catalyst paste and a base paste). Equal amounts of catalyst and base are mixed and applied with a Dycal applicator directly to the deepest points of dentin in the cavity. Excess Dycal material will be removed from the cavity walls and enamel margins. Then Light Cure glass ionomer cement is placed in the cavity as a base.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Faculty of Dentistry

Full name of responsible person

Mitra Yadolahi

Street address

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Elham Raeisi

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Building no2,University Headquarters,Kashani Boulevard

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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Shamim Mohammadi
Position
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Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The clinical study report will be published as an article

When the data will become available and for how long

It is possible to start accessing immediately after printing the results

To whom data/document is available

Access is open to the public

Under which criteria data/document could be used

For more information

From where data/document is obtainable

Fadak Complex, Hamedanian St. ,Hasht Behesht St. ,Isfahan Shamim Mohammadi khorshid_mohammad@yahoo.com 09134432263

What processes are involved for a request to access data/document

The clinical study report will be available to the public immediately after printing. For detailed information, send an email to khorshid_mohammad@yahoo.com. The data files will reach the applicant after 1 month.

Comments