Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of clinical and radiographic effects of a new calcium silicate cement with Mineral trioxide Aggregate cement in vital pulp therapy as direct pulp cap in teeth with closed apex

Protocol summary

Study aim

Determination of clinical and radiographic effects of a new calcium silicate cement with aggregate mineral trioxide in the treatment of live pulp by direct pulp cap in teeth with adult apex

Design

This study was a clinical trial with a control group, with a factorial group, one-way blind, random sampling and purpose-based sampling on 90 patients using software for randomization.

Settings and conduct

The study will be performed in Year 1401 in the endodontics department of Zahedan Dental School Unilateral blinding is performed for patients after full knowledge of the harms and benefits of all 3 types of treatment

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between 12 and 50 years of age with Vital molars with closed apex and a history of pain indicating irreversible pulpitis with or without clinical signs who are ready and able to attend follow-up sessions and have signed the consent form. Conditions of non-admission: Patients with mental disabilities, pregnant patients, patients with systemic diseases, patients with teeth with a history of trauma or resorption, patients taking analgesics in a few days before the study

Intervention groups

1-Root canal treatment: preparation of access cavity, preparation of canals, ablation of canals with 2% gutta-percha and Ah26 sealer, covering the orifice area with glass inomer 2-direct pulp cap with MTA cement: removal of caries with sterile bur after complete isolation of the tooth, stopping of pulp hemorrhage with 2.5% sodium hypochlorite, direct coating of pulp with MTA cement 3-Direct pulp cup with new cement:This group is exactly the same as the second group and the only difference is the use of new cement

Main outcome variables

pain; clinical signs of soft tissue;Peripheral radiographic signs; response to sensibility tests

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220519054917N1**
Registration date: **2022-06-03, 1401/03/13**
Registration timing: **prospective**

Last update: **2022-06-03, 1401/03/13**
Update count: **0**

Registration date

2022-06-03, 1401/03/13

Registrant information

Name

Seyed Mohammad Javad Aslani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of clinical and radiographic effects of a new calcium silicate cement with Mineral trioxide Aggregate cement in vital pulp therapy as direct pulp cap in teeth with closed apex

Public title
Clinical and radiographic effects of a new calcium silicate cement in vital pulp therapy in teeth with close apex
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Vital molar teeth (positive response to electrical pulp tester and cold test before treatment and objective observation of pulp bleeding after preparation of access cavity) History of irreversible pulpitis (history of spontaneous or localized pain; irritation due to cold and heat that persists after stimulus removal; pain induced by cold test) or no clinical signs of irreversible pulpitis but with Pulp exposure after removal of caries Patients are in the age range of 12 to 50 years Prepared and able to attend follow-up meetings Patients have signed a consent form
Exclusion criteria:
Patients with systemic diseases in which tissue repair is impaired, such as diabetes, cancer, endocrine disorders, AIDS, and those taking corticosteroids. Patients who for any reason can not inject anesthesia containing epinephrine Pregnant or lactating women. Patients with mental and physical disabilities. Patients with poor oral hygiene and periodontal disease in such a way that long-term tooth retention is not possible due to periodontal problems. People like immigrants from other countries who have a great chance of leaving the study. Age of patients less than 12 years (for the treatment of the first molar) and less than 15 years (for the treatment of the second molar) and more than 50 years. Lack of control of pulpal hemorrhage in highly inflamed teeth.(Pulp bleeding can not be controlled by placing a cotton swab dipped in 5.25% sodium hypochlorite in the chamber pulp for a maximum of ten minutes). Teeth that can not be restorated with the usual class one and two restorations with or without cusp reduction. Teeth with localized periodontal disease in a way that the survival of the tooth is not in danger, but due to exposure of the root surface, there is a possibility of pulpal stimulation and disruption of the restoration process. Teeth with external, internal resorption or visible pulp calcifications on periapical radiography Traumatized teeth Teeth with swelling of adjacent soft tissue Teeth with open apex Teeth with pericardial lesion (around the apex or forca area) visible on radiography Taking antibiotics in a recent month Taking painkillers in the last 3 days Existence of defects in restoration in follow-up sessions
Age
From **12 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
After the initial selection of eligible patients and its approval by the relevant resident at Zahedan Dental School, the patient will be given the necessary explanations about the implementation of the plan (how to participate, program details, schedule of the plan, types of treatment plans). If the patient wishes and approves, the patient will be provided with an adjusted consent form, which the patient will sign after the study. In this way, the patient is considered as a patient included in the plan and their treatment will be done either in the same session or in another session. 3 groups will be studied and the number of teeth to be treated; In each group, we consider 30 people and finally the total sample size is 90 people. 3 study groups including the first group: root canal treatment, the second group: direct pulp cup with MTA cement, the third group: direct pulp cup with new cement Patients are aware of the process of all three treatments and the advantages and disadvantages of all three treatments and are told that one of these three treatments is done for them randomly but patients do not know which treatment is done for them.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of zahedan University of Medical Sciences
Street address
Zahedan, East Azadegan St., School of Dentistry, Endodontics Department
City
Zahedan
Province
Sistan-va-Balouchestan

Postal code
9817699693
Approval date
2022-04-17, 1401/01/28
Ethics committee reference number
IR.ZAUMS.REC.1401.040

Health conditions studied

1

Description of health condition studied
irreversible pulpitis
ICD-10 code
K04.2
ICD-10 code description
Pulp degeneration

Primary outcomes

1

Description
pain
Timepoint
At intervals of 6, 12, 24 hours and then daily for a week
Method of measurement
Based on the pain recorded on the VAS pain index ruler

2

Description
Clinical signs of soft tissue around the roots
Timepoint
6 months after treatment
Method of measurement
Inflammation, redness, swelling and infection of the soft tissue adjacent to the tooth, spontaneous pain, pain on touch and knock, fistula and abscess

3

Description
Symptoms of periapical radiography
Timepoint
Follow-up periods are one week and six months.
Method of measurement
It is ranked based on the presence of pdl widening and radiolucency or the absence of any reaction. Existence of internal and external root resorption, apical lesion and canal calcification

4

Description
The pulp condition of the treated tooth
Timepoint
Follow-up periods are one week and six months.
Method of measurement
It is determined based on EPT and cold tests

5

Description
Periapical conditions of the treated tooth
Timepoint
Follow-up periods are one week and six months.
Method of measurement
Based on the response to the percusion and touch tests and the radiographic appearance of the desired tooth is determined

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Direct pulp cap with MTA cement: After confirming the complete anesthesia of the pulp with a sterile bur, first a large part of caries and weak enamel structures were removed and after complete isolation of teeth the caries near the pulp chamber was removed by new steril bur.To control bleeding, 5.25% cotton soaked in hypochlorite is used for a maximum of 10 minutes until a clean, clot-free pulp wound and bleeding are observed at the site of pulpal exposure.At this stage, MTA cement is prepared according to the factory instructions and with a thickness of 2 to 3 mm, with a gentle pressure of a dry and sterile cotton, it will be placed in the place of pulp exposure to be compatible with the walls. Excess cement is removed from the walls with a damp cotton swab, and a wet cotton swab will be in place for five minutes after making sure it is suitable (creating a white marble surface without lumps and cracks and distance from the walls). Then immediately cover it with a 2 mm of light cure glass inomer and it will be repaired with tooth-colored materials.
Category
Treatment - Other

2

Description
Intervention group: Intervention group: Direct pulp cap with new cement: This intervention method is exactly the same as the direct pulp coating group with MTA cement and the only difference is the use of new cement in which cement powder is synthesized by Sol-gel method and zirconium oxide is added as Appasifiers and pectin as plant-based polymers with calcium chloride as a liquid for the preparation of dental cement
Category
Treatment - Other

3

Description
Control group: Root canal treatment: First, all caries and weakened enamel structures are removed and the access cavity is fully accessed. Then the preparation is

done using nickel-titanium filtration file and electric motor. After drying the channels with a paper cup of the same size as the original gutta, the channel will be filled with lateral compaction technique using AH26 sealer. After filling the channels, the entrances will be covered with a 2 mm layer of resin modified glass inomer

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Dental School

Full name of responsible person

Seyed Mohammad Javad Aslani

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East Azadegan St. - School of Dentistry

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakhshani

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Seyed Mohammad Javad Aslani

Position

Endodontics Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Seyed Mohammad Javad Aslani

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position
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Medical doctor

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Information about the main outcome and its comparison with different groups can be shared.

When the data will become available and for how long
Access period starts 6 months after the results are published.

To whom data/document is available
Researchers working in academic and scientific institutes, dental students, dentists.

Under which criteria data/document could be used
If the data are used to improve vital pulp therapy treatments and replace nationally produced biomaterials with similar foreign products in order to be self-sufficient and reduce costs and improve treatment results, all dental researchers will be able to access the data.

From where data/document is obtainable
Dr.Seyed Mohammad Javad Aslani Email: Aslani.j1370@gmail.com Mobile: +989177179907

What processes are involved for a request to access data/document
Please send an email to the respondent and state the resume and purpose of accessing the data for the respondent.

Comments