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Efficacy of calcium-enriched mixture cement, mineral trioxide aggregate and calcium hydroxide used as direct pulp capping agents in deep carious lesions - a randomised clinical trial.

Submission date
21/06/2022

Recruitment status
No longer recruiting

Registration date
11/08/2022

Overall study status
Completed

Last Edited
17/09/2024

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Preservation and maintenance of the life of the tooth by promoting healing of the pulp is one objective in Endodontics. Historically, the placement of a medicament or material against the exposed pulp during the removal of tooth decay has been considered controversial, and instead, root canal therapy has been recommended. Root canal therapy involves the removal of the entire tooth pulp to eliminate pain. But during this procedure, the tooth is literally becoming dead. Multiple appointments, painful procedures, the need for multiple X rays, the need for a dental crown and increased treatment expenses are other drawbacks of this procedure. Furthermore in this procedure, the pulp is not given an opportunity to heal.
The purpose of this study is to add knowledge to the existing literature in the field of Vital Pulp Therapy about the effectiveness of CEM cement, MTA, and Calcium hydroxide in maintaining the life of the wounded pulp by promoting healing and repair when applied over the pulp after removal of the entire decayed portion.

Who can participate?
Patients aged 14 – 60 years with tooth decay affecting the tooth pulp, causing inflammation.

What does the study involve?
The teeth are divided into 3 groups of 50 patients each.
1. Calcium Enriched Mixture (CEM cement) applied to the pulpal wound after removal of tooth decay.
2. Mineral Trioxide Aggregate (MTA) applied to the pulpal wound after removal of tooth decay.
3. Calcium Hydroxide (Dycal) applied to the pulpal wound after removal of tooth decay.
The treated tooth will be filled permanently using tooth coloured filling in the same appointment.
The treated tooth will be evaluated for any pain or discomfort at 1 month, 3 months, 6 months, 12 months and 18 months after the procedure. In the event of any pain or discomfort root canal treatment will be done.

What are the possible benefits and risks of participating?
A successful direct pulp capping procedure will preserve the vitality of the dental pulp thereby eliminating the need for more invasive treatment options like root canal therapy or extraction of the caries exposed tooth. Possible risks involve worsening of pain that may require root canal therapy of the involved tooth.

Where is the study run from?
Department of Conservative dentistry and Endodontics, Government Dental College Kozhikode (India)

When is the study starting and how long is it expected to run for?
November 2011 to September 2012

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Mridula Parameswaran, mridulatdc@gmail.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers

Nil known

Study information

Scientific Title
Comparative evaluation of calcium enriched mixture (CEM cement) with mineral trioxide aggregate and calcium hydroxide used as direct pulp capping agents- an in vivo study

Acronym
CECMCD

Study objectives
Is there any difference in the efficacy of Calcium Enriched Mixture (CEM) cement in maintaining pulp vitality following direct pulp capping of carious teeth with reversible pulpitis when compared to Mineral trioxide aggregate (MTA) and Calcium Hydroxide?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/03/2011, Institutional Ethics Committee Government Dental College Kozhikode (673008 Kerala, India; +91 9447776977; no email provided), ref: ECR/673/Inst/KL/2014/RR-20

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Patients complaining of pain in relation to deep carious lesions while having food or drinks diagnosed clinically and radiographically to be having reversible pulpitis.

Interventions
The study includes 150 patients selected from the Out Patient Department Of Conservative Dentistry & Endodontics, Govt. Dental College Kozhikode with symptoms of reversible pulpitis in relation to deep carious lesions in close proximity to the pulp.
The teeth are divided into 3 groups of 50 patients each. Randomisation was done by drawing

lots.
Group C (Experimental group) – Direct pulp capping with Calcium Enriched Mixture (CEM cement)
Group M (Control group)- Direct pulp capping with Mineral Trioxide Aggregate (MTA)
Group D (Control Group)- Direct pulp capping with Calcium Hydroxide (Dycal)

Capping material overlaid with a thin protective layer of self curing glass ionomer base followed by permanent restoration with direct posterior composite resin immediately. Recall examinations at 1 month, 3 months, 6 months, 12 months and 18 months intervals.

Intervention Type
Procedure/Surgery

Primary outcome measure
The criteria for success and failure of direct pulp capping were assessed based on clinical and radiographic findings at each of the follow-up periods at 1 month,3 months, 6 months, 12 months and 18 months in comparison to the preoperative clinical and radiographic data.
1. Pain in relation to the capped tooth assessed using the Visual Analog Scale (VAS) graded from 0-10 recorded and compared in each of the follow up examinations.
2. Tenderness to percussion and palpation- present or absent
3. Measurement of probing depth in each of the follow up examinations using WHO probe.
4. Mobility of tooth assessed using blunt end of two mouth mirrors and graded as 1 to 3
5. Vitality was assessed on the tooth treated using cold test (ENDO FROST PULP TESTER) and Electric pulp tester (Gentle –Pulse Pulp vitality tester, Parkell Electronics,Farmingdale, NY, USA) and scores assigned from 0-10 in relation to adjacent and contralateral teeth and compared with the previous scores in each of the follow up examinations
6. Radiographic evaluation included assessment of the periradicular condition of the selected teeth using Peri Apical Index Scoring System (PAI Score.)

Secondary outcome measures
At 1 month,3 months, 6 months, 12 months and 18 months
1. Whether root canal therapy done in any of the follow up examinations yes/no
2. Whether extraction done in any of the follow up examinations yes/no
3. Whether sinus tract present or absent yes/no
4. Whether root resorption present or absent yes/no

Overall study start date
21/03/2011

Completion date
21/09/2012

Eligibility

Key inclusion criteria
1. Teeth having deep carious lesion approximating the pulp.
2. Have symptoms of reversible pulpitis which includes provoked pain of short duration which was relieved upon removal of the stimulus in relation to the carious tooth.
3. No history of spontaneous pain or tenderness to percussion.
4. Patients in the age group of 14- 60 years who are apparently healthy and free of any systemic disease and are not under any medication.
5. Good oral health.

6. Positive response to cold test and electric pulp test
7. Periapical Index Score (PAI) = 1 indicating normal periradicular structures.
8. Teeth which are not subjected to traumatic or abnormal functional stresses.
9. Absence of any non carious destructions and developmental defects
10. No appreciable mobility to finger pressure
11. No clinical or radiographic evidence of pulp degeneration
12. Absence of profuse haemorrhage from the exposure site.
13. Absence of serous or purulent exudates from the exposure site.
14. Control of haemorrhage is possible at the exposure site in less than 5 minutes

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Total final enrolment
150

Key exclusion criteria
1. Patients with compromised immune status
2. Patients who are pregnant at the time of follow-up
3. Caries have extensively penetrated the pulp chamber
4. Tooth showing symptoms of irreversible pulpitis
5. Bleeding from the exposure site persists for more than 5 minutes

Date of first enrolment
22/03/2011

Date of final enrolment
21/09/2012

Locations

Countries of recruitment
India

Study participating centre
Department of Conservative dentistry and Endodontics, Government Dental College Kozhikode
Government Dental College Kozhikode
Kerala

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Sponsor information

Organisation
Government Dental College

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.gdckozhikode.org

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high -impact peer- reviewed journal

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and analysed during the current study are not expected to be made available due to confidentiality of patient data

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/07/2023	17/09/2024	Yes	No