ISRCTN38899178 https://doi.org/10.1186/ISRCTN38899178

The effectiveness of biomaterials filling for protecting exposed dental pulp

Submission date
29/04/2024

Recruitment status
No longer recruiting

Registration date
01/05/2024

Overall study status
Completed

Last Edited
01/05/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Direct pulp capping (DPC) is a dental procedure that aimed to protect the vital exposed pulp. The aim of this study is to evaluate the clinical and radiographical success rate of 3 DPC bioceramic materials (TotalFill Fast Set Putty, TotalFill Paste, and Neo Putty) on vital permanent teeth compared to golden standard DPC material (Neo MTA Plus).

Who can participate?
Adult patients aged 15-25 years old with deep carious lesions on permanent teeth.

What does the study involve?
Participants will be randomly divided into 4 groups to be treated with Neo MTA Plus, TotalFill Fast Set Putty, TotalFill Paste, and Neo Putty as DPC materials. All the teeth will be evaluated clinically and radiographically for up to 1 year.

What are the possible benefits and risks of participating?
Because of the complexity of the root canal system in primary teeth, preserving dental pulp appears to be more effective than complete root canal treatment and obturation due to the potential complications following endodontic treatment. In addition, we assessed the impact of modern bioceramic materials (which exhibit suitable consistency and ease of use) on the human dental pulp.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
June 2020 to December 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UDDS-380-22062020/SRC-89

Study information

Scientific Title
The ability of new bioceramic materials used in direct pulp capping in repairing dentine pulp complex: a randomized controlled trial

Study objectives
This study is designed to assess the hypothesis that new bioceramic materials can be used as direct pulp capping materials on exposed pulps in teeth with deep carious lesions as an alternative to the golden standard material (MTA) in the term of clinical and radiographical success and evaluating their potential for pulp healing clinically and radiographically

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 22/06/2020, Damascus University (Almazzeh ST, Damascus, 20872, Syria; +963 (0) 90404840; Osama.aljabban@gmail.com), ref: 380

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Deep carious lesions in asymptomatic permanent teeth

Interventions
Forty asymptomatic closed-apex teeth in healthy patients aged between 15-25 years were randomly divided into four groups using http://www.randomization.com:
Group A (control): teeth will be treated with Neo MTA Plus as direct pulp capping therapy.
Group B (study): teeth will be treated with Neo Putty as direct pulp capping therapy.
Group C (study): teeth will be treated with Total Fill Paste as direct pulp capping therapy.
Group D (study): teeth will be treated with Total Fill Fast Set Putty as direct pulp capping therapy.

The intervention steps were as follows:
Administer local anesthesia.
Apply rubber dam isolation on the tooth being studied.
Prepare a cavity of appropriate depth for pulp exposure with a size of 1 mm and a width of approximately 2 mm, lingually or buccolingually.
Continuous irrigation and washing with physiological saline.
Control bleeding by applying pressure with a cotton roll at the exposure site.
Appling the studied material (according to the randomization) as a direct pulp capping material.
Restoring the cavity with resin bonded restoration.

Intervention Type
Other

Primary outcome measure
1. Clinical evaluation: Patients of both groups were recalled after 7 and 30 days of treatment and during radiographical assessment periods (1, 6 and 12 months), where they were asked to rate their pain on the following:

0 No pain.
1 Mild pain.
2 Moderate pain.
3 Severe pain.
2. Radiographical assessment: After coronal restoration was completed a radiograph was taken immediately (R0), After 1 month (R1), After 6 months, and After 12 months (R2). The integrity of the periapical tissue was assessed. Moreover, the following values were given to evaluate the degree of formation of the dentinal bridge radiographically:
0 No dentinal bridge
1 The dentinal bridge begins to form
2 There is complete formation of the dentinal bridge

Secondary outcome measures
1. Patient age (in years) and sex (male or female) determined during patient examination at the start of treatment
2. Required time for bleeding control of each case (in minutes) measured using a timer.

Overall study start date
22/06/2020

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Teeth with closed apex.
2. No history of trauma.
3. Healthy patients.
4. No radiographic or clinical signs of periapical lesions.
5. Radiographic or clinical symptoms of pulpal necrosis are present.
6. Positive vitality testing (Vital pulp).

Participant type(s)
Patient

Age group
Adult

Lower age limit
15 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Presence of any clinical or radiographic symptoms of acute pulpitis or necrosis.
2. Patients with systematic disease.

Date of first enrolment
22/06/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University-Department of Endodontics
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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ROR

https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

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

Intention to publish date
01/07/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication