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Can new dental fillings induce regeneration of damaged teeth?

Submission date	Recruitment status	[ ] Prospectively registered
16/04/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/05/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/07/2022	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this study is to investigate a potential therapeutic role for a new group of dental filling materials – Biodentine and ProRoot MTA – in stimulating the repair of the dental pulp or 'nerve' of the tooth. This material has recently demonstrated benefits over traditionally used filling materials and has been now been marketed specifically for its role in treating deep decay and exposed pulp tissue. The tooth which you are to have extracted can be used to investigate this potential.

Who can participate?
Male or female aged 10-60 years (patients under 18 years with the consent of parent/guardian).

What does the study involve?
Participants will be randomly allocated to receive a direct pulp capping procedure using MTA or Biodentine. After 6 months the tooth is removed for evaluation.

What are the possible benefits and risks of participating?
There are no adverse risks.
There are general benefits in that you will be contributing to original research in an area with a potential therapeutic benefit for patient care. There are no risks from participation.

Where is the study run from?
Dublin Dental University Hospital (Ireland)

When is the study starting and how long does it run for?
April 2017 to May 2022

Who is funding the study?
Trinity College Dublin (Ireland)

Who is the main contact?
Professor Hal Duncan (Hal.Duncan@dental.tcd.ie)

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
Experimental pulp capping with hydraulic calcium silicate cements induces a range of responses including regeneration of tubular dentine

Acronym
Nil known

Study objectives
The objectives were to study the nature and the quality of the mineralised bridge and soft tissue response after application of Biodentine and MTA after longer term 6-month intervals; to analyse the presence of bacteria adjacent to the capping material and in the pulp tissue and finally to assess the morphological nature of the cells in contact with the mineralised bridge.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/04/2017, St James's Hospital REC (Tallaght Hospital, Tallaght, Dublin 24, Ireland; +353 1 4142199; Sadhbh.ONeill@tuh.ie), ref: 2017/04/01

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Treatment of disease of the dental pulp

Interventions
Direct pulp capping procedure using MTA or Biodentine. MTA is the control/gold standard. After 6 months the teeth were extracted and histologically evaluated.
Random sequence generation was performed using a computer-generated number (www.random.org) and to provide allocation concealment a dental nurse not involved in the recruitment of patients carried out the online randomisation. The virtual coin was 'flipped' before each appointment to decide which material should be used.

Intervention Type
Other

Primary outcome measure
Dental hard tissue bridge formation: Histology at 6 months

Secondary outcome measures
Discoloration: Photographed at 6 months

Overall study start date
25/04/2017

Completion date
01/05/2022

Eligibility

Key inclusion criteria
Male or female patients aged between 14-50 years (patients under 18 years required the consent of a parent/guardian) with an experimental tooth responding positively to pulp sensibility testing (cold thermal and electric), which was scheduled for extraction. The tooth was to be extracted for either orthodontic or prevention reasons and needed to be completely caries-free.

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
16

Total final enrolment
21

Key exclusion criteria
Teeth excluded from participation in the trial were: non-vital or carious teeth, teeth that could not be isolated with a rubber dam or teeth that required sectioning of the roots in order to be extracted.

Date of first enrolment
01/08/2017

Date of final enrolment
01/06/2021

Locations

Countries of recruitment
Ireland

Study participating centre
Trinity College Dublin
Dublin Dental University Hospital
Division of Restorative Dentistry & Periodontology
Lincoln Place
Dublin
Ireland
Dublin 2

Sponsor information

Organisation
Dublin Dental University Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.dentalhospital.ie/

ROR
https://ror.org/03v4j0e89

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Dublin Dental University Hospital

Results and Publications

Publication and dissemination plan
Planned publication in high impact factor journal 'International Endodontic Journal' and international presentation

Intention to publish date
01/07/2023

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		01/03/2017	20/04/2022	No	Yes