

# Can new dental fillings induce regeneration of damaged teeth?

<b>Submission date</b> 16/04/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/05/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/07/2022	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

## Contact name

Prof Henry Duncan

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# Additional identifiers

# 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; Sadbh.ONeill@tuh.ie), ref: 2017/04/01

## Study design

Interventional randomized controlled trial

## Primary study design

Interventional

**Study type(s)**

Treatment

**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(s)**

Dental hard tissue bridge formation: Histology at 6 months

**Key secondary outcome(s)**

Discoloration: Photographed at 6 months

**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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**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

**ROR**

<https://ror.org/03v4j0e89>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Dublin Dental University Hospital

# Results and Publications

## 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?
<a href="#">Participant information sheet</a>		01/03/2017	20/04/2022	No	Yes