

# Partial pulpotomy in permanent teeth

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<b>Registration date</b> 25/02/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/09/2017	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

A partial pulpotomy is a dental procedure where the diseased part of the pulp of a tooth (the inside of the tooth containing nerves, blood vessels and connective tissue) is removed and the gap filled with a type of medicate filling. It is hoped that by only removing part of the pulp, the pulp that remains stays alive (and therefore keeping the tooth alive as well). This study compares the performance of three different kinds of filling, namely ProRoot MTA (the usual treatment) OrthoMTA and RetroMTA when placed in permanent teeth.

### Who can participate?

Patients that need to have a partial pulpotomy.

### What does the study involve?

Participants are randomly allocated to one of three groups. Those in group 1 (control) have a partial pulpotomy and are treated with proRoot MTA. Those in group 2 have a partial pulpotomy and are treated with OrthoMTA. Those in group 3 have a partial pulpotomy and are treated with RetroMTA. Clinical examination and radiographic comparisons are carried out 1, 3, 6 and 12 months after the treatment.

### What are the possible benefits and risks of participating?

There is a possibility that partial pulpotomy treated with these MTA materials may help to save the vital pulp without root canal treatment. There is a small risk of pulp canal narrowing after this type of procedure.

### Where is the study run from?

Yonsei University Dental Hospital (South Korea)

### When is the study starting and how long is it expected to run for?

December 2012 to October 2015

### Who is funding the study?

Ministry of Health and Welfare (South Korea)

Who is the main contact?  
Professor Yooseok Shin  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
A randomized controlled trial of ProRoot MTA, OrthoMTA and RetroMTA for partial pulpotomy in permanent teeth

**Study hypothesis**  
The clinical and radiographic outcomes of partial pulpotomy using ProRoot MTA, OrthoMTA and RetroMTA might be shown differences on exposed pulp tissue of human permanent teeth

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Yonsei University Dental Hospital, ref: 2-2012-0053

**Study design**

Single centre randomised single-blind controlled study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Condition**

Permanent teeth with advanced caries or dental trauma with pulp exposure

**Interventions**

Participants have vital permanent teeth with advanced caries or dental trauma with pulp exposure that require root canal treatment. After application of local anaesthesia and rubber dam isolation, the carious dentin was completely removed in these teeth. After the partial pulp amputation (partial pulpotomy), the preparation is thoroughly disinfected with NaOCl.

After the control of hemorrhage. MTA materials were used in pulp sites. All procedure were performed with one visit treatment. Participants are randomly allocated to one of the three following groups:

1. Control group - participants receive proRoot MTA
2. Experimental group 1 - participants receive OrthoMTA
3. Experimental group 2 - participants receive RetroMTA

Clinical examination and radiographic comparison were carried out at 1, 3, 6 and 12 months after the treatment.

**Intervention Type**

Drug

**Phase**

Phase IV

**Drug/device/biological/vaccine name(s)**

1. ProRoot MTA
2. OrthoMTA
3. RetroMTA

**Primary outcome measure**

Patients are recalled for the following clinical and radiographical examinations:

1. Spontaneous pain and/or sensitivity (Visual Analogue Scale  $\geq 1$ , symptomatic)
2. Periodontal conditions (gingival redness and swelling)
3. Periapical radiolucency
4. Pathological root resorption

Assessed at 1, 3, 6 and 12 months.

### **Secondary outcome measures**

N/A

### **Overall study start date**

10/12/2012

### **Overall study end date**

30/10/2015

## **Eligibility**

### **Participant inclusion criteria**

1. Tooth has no history of spontaneous pain
2. Tooth has acute minor pain that subsides with analgesics
3. Tooth has no discomfort to percussion, no vestibular swelling and no mobility
4. Radiographic examination shows normal appearance of periodontal attachment
5. Pulp is exposed during caries removal or subsequent to recent trauma
6. Tissue appears vital
7. Bleeding from the pup excision site stops with NaOCl within 5 minutes

### **Participant type(s)**

Patient

### **Age group**

All

### **Sex**

Both

### **Target number of participants**

82 patients

### **Participant exclusion criteria**

Crown fracture and pulp necrosis

### **Recruitment start date**

10/12/2012

### **Recruitment end date**

30/09/2014

## **Locations**

**Countries of recruitment**

Korea, South

**Study participating centre**

**Yonsei University Dental Hospital**

50-1 Yonsei-ro Seodaemungu

Seoul

Korea, South

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## **Sponsor information**

**Organisation**

Yonsei Dental Hospital

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**Sponsor type**

University/education

**ROR**

<https://ror.org/02fzwdc59>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Ministry of Health and Welfare

**Alternative Name(s)**

Ministry of Health and Welfare, Taiwan, , MOHW

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Taiwan

**Funder Name**

National Research Foundation of Korea

**Alternative Name(s)**

, National Research Foundation (South Korea), NRF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Korea, South

## **Results and Publications**

**Publication and dissemination plan**

International endodontic journal (plan)

**Intention to publish date**

01/04/2016

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Available on request