

Partial pulpotomy in permanent teeth

Submission date 24/02/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/09/2017	Condition category 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

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?
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Contact information

Type(s)
Scientific

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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 objectives
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**Health condition(s) or problem(s) studied**

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 ≥ 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

Completion date

30/10/2015

Eligibility

Key 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

Key exclusion criteria

Crown fracture and pulp necrosis

Date of first enrolment

10/12/2012

Date of final enrolment

30/09/2014

Locations

Countries of recruitment

Korea, South

Study participating centre

Yonsei University Dental Hospital

50-1 Yonsei-ro Seodaemungu

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Sponsor information

Organisation

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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