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Partial pulpotomy in permanent teeth

Submission date
24/02/2016

Recruitment status
No longer recruiting

Registration date
25/02/2016

Overall study status
Completed

Last Edited
25/09/2017

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
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

Protocol serial number
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 Hospita, ref: 2-2012-0053

Study design
Single centre randomised single-blind controlled study

Primary study design
Interventional

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
N/A

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

Healthy volunteers allowed
No

Age group
All

Sex
All

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
Yonsei Dental Hospital

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request