

PATIENT INFORMATION SHEET

1. Study Information

Protocol Title:

Regenerative Endodontic Therapy (RET) using Antibiotic pastes or Calcium Hydroxide disinfection for the management of immature non-vital permanent teeth in children: A Randomized Controlled Clinical Trial

Principal Investigator & Contact Details:

NUH Dental Centre:

Dr Tong Huei Jinn

Discipline of Orthodontics and Paediatric Dentistry,

Faculty of Dentistry, National University of Singapore,

11 Kent Ridge Road, Singapore 119083

Telephone: 67724989 extension 1788

Mobile: 91719755

School Dental Service, HPB:

Dr Lim Wanyi

School Dental Service

Health Promotion Board

Level 4, 3 Second Hospital Ave, Singapore 168937

Telephone: (65) 64353147

Mobile: 98340174

Study Sponsor:

National University of Singapore, AcRF Tier 1, Faculty Research Grant

2. Purpose of the Research Study

You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this research study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You are invited because you are (i) fit and healthy, (ii) have a non-vital/infected immature (young) permanent tooth which requires root canal treatment, (iii) are not allergic to Ciprofloxacin or Metronidazole antibiotics or Calcium Hydroxide, and (iv) are between 6- 16 years old. You will be followed up for 18 months from the date of completion of treatment. This study is carried out to find out the success of Regenerative Endodontic Therapy in the management of non-vital immature (young) teeth using two different types of medications for disinfection of the root canal: either a combination of antibiotics (Ciprofloxacin and Metronidazole) or Calcium Hydroxide. A successful outcome would be a tooth which is free from pain and infection, with possible continued growth of the root.

This study will recruit 60 subjects from School Dental Service, Health Promotion Board or National University Hospital over a period of 3 years.

3. What procedures will be followed in this study

If you take part in this study, you will be randomized to receive either Antibiotics or Calcium Hydroxide medication to disinfect the root canal. Randomization means assigning you to one of 2 groups by chance, like tossing a coin or rolling dice.

If you take part in this study, you will undergo root canal treatment according to the protocol in the study. This involves numbing the tooth with local anaesthesia, and removing the dead dental pulp (nerve) within the tooth and cleaning the root canal with disinfectant solutions. Either antibiotics or Calcium hydroxide medicament will be placed into the root canal to further disinfect the tooth for 4 weeks +/- 7 days. The treatment protocol used will be allocated to you, i.e. you will also not be allowed to choose the protocol used for the treatment. Each treatment session will be about 60 minutes.

You will have to come back for a second visit and we will evaluate the tooth for signs and symptoms of on-going infection. If there are still signs of infection, the same disinfection procedure will be repeated. If the tooth is free of infection, we will proceed with the second stage of the root canal process which involves inducing bleeding into the root canal. The root canal will then be sealed with a permanent filling. All procedures will be carried out under local anaesthesia.

Following this visit, you will be reviewed at 3 months, 6months, 9months, 12 months, 15 months and 18 months (buffer time is +/- 2 weeks for each review visit) following completion of treatment. This review frequency is the same as any root canal procedure. You will also be asked to help fill in a questionnaire on your pain experience and how this treatment has affected your daily life (if any).

Digital X-rays will be taken before and after treatment, as well as during every follow up visit to monitor the development of the tooth as well as for signs of healing of the infection.

Your participation in the study will last 2 years. You will have to attend 2-3 treatment visits, which will be conducted over 2-3 months. You will then be followed up for 18 months after the treatment is done at 3 monthly intervals. You will need to visit the dentist's office a total of 8-9 times in the course of the study.

4. Your Responsibilities in This Study

If you agree to participate in this study, you should follow the advice given to you by the study team. You should be prepared to visit the hospital for at least 2 treatment visits and 6 review visits every 3 months and undergo all the procedures that are outlined above.

5. What Is Not Standard Care or is Experimental in This Study

The study is being conducted because we do not know which of the two medicines has a better success rate for treatment of subjects with young teeth and dead nerves (i.e. non-vital immature teeth). We hope that your participation will help us to determine which of these two

treatment is more superior.

6. Possible Risks and Side Effects

All treatment will be done under local anaesthesia. As with all root canal procedures, you might experience slight discomfort following the treatment. This can be controlled by taking painkillers, e.g. Panadol (Paracetamol).

Also, as antibiotics may be used as part of the disinfection process, there is a small risk that you might be allergic to the antibiotics. Careful medical history will be taken prior to the procedure to ensure that you are not allergic to the antibiotics used. If you have a history of allergies to either Fluoroquinolones or Ciprofloxacin (Tradenames: Ciloxan, Ciprobay, Neofloxin) or Metronidazole (Tradenames: Flagyl, Filmet), please let us know and you will not be enrolled in this study.

As with all treatment, there is a risk that the tooth may not respond to treatment, or symptoms of re-infection may arise. Should this occur, then you will be referred to a tertiary institution for conventional root canal treatment (apexification method) using Mineral Trioxide Aggregate (MTA). The cost of this treatment will be borne by you.

The common side effects of root canal treatment may include transient post-operative discomfort following cleaning and disinfection of your infected tooth. Usual post-operative instructions include a course of over-the-counter paracetamol. You may find it more comfortable not to chew harder foods on the affected side of the mouth during the first 1-2 days after treatment.

The dosage of X-ray radiation when taking a dental X-ray is typically small, equivalent to a few days' worth of background environmental radiation exposure, or similar to the dose received during a cross-country airplane flight (concentrated into one short burst aimed at a small area).

7. Possible Benefits from Participating in the Study

There is no guarantee of benefit to you if you participate in this trial. The knowledge gained will help the dentists understand the efficacy of the antibiotics used and success of this treatment, which may be of benefit to other parents and children.

8. Alternatives to Participation

Yes, you have the right to refuse any form of participation in this research and your decision will not affect your dental management or cause you any rightful benefits. If you choose not to take part in this study, you will receive standard care for your condition. In our institution this would be referral to a tertiary institution (e.g. National Dental Centre or National University Hospital) for root canal treatment (apexification method) using Mineral Trioxide Aggregate (MTA). In this traditional treatment method, the tooth will not continue to grow or thicken.

9. Costs & Payments if Participating in the Study

If you take part in this study, the following will be performed at no charge to you: All treatment costs, review charges and X-ray costs. These costs will be borne by the institution.

10. Voluntary Participation

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study, you will be required to contact the Principle Investigators: Dr Tong Huei Jinn (denthj@nus.edu.sg) or Dr Lim Wanyi (LIM_Wanyi@hpb.gov.sg) . However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your doctor, the Investigator and/or the Sponsor of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the doctor will decide if you may continue in the research study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legally acceptable representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative.

11. Compensation for Injury

If you follow the directions of the doctors in charge of this study and you are physically injured due to the trial substance or procedure given under the plan for this study, the National University Hospital or Health Promotion Board will pay the medical expenses for the treatment of that injury.

The National University Hospital or Health Promotion Board will without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove that the National University Hospital or Health Promotion Board is at fault. There are however conditions and limitations to the extent of compensation provided. You may wish to discuss this with your Principal Investigator.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

12. Confidentiality of Study and Medical Records

Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available.

However, the National University Hospital or Health Promotion Board, Regulatory Agencies (Health Science Authority) and NHG Domain-Specific Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and

data, without making any of your information public. By signing the Informed Consent Form attached, you are authorizing (i) collection, access to, use and storage of your “Personal Data, and (ii) disclosure to authorised service providers and relevant third parties.

“Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. This includes medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this Personal Data, will be subject to review by the relevant institutional review board. By participating in this research study, you are confirming that you have read, understood and consent to the Personal Data Protection Notification available at: <http://www.nuhs.edu.sg/personal-data-protection.html>

Data collected and entered into the Case Report Forms are the property of the National University Hospital, the National University of Singapore and Health Promotion Board. In the event of any publication regarding this study, your identity will remain confidential.

13. Who To Contact if You Have Questions

If you have questions about this research study, you may contact the Principal Investigators:

NUH Dental Centre:

*Dr Tong Huei Jinn
Discipline of Orthodontics and Paediatric Dentistry,
Faculty of Dentistry, National University of Singapore,
11 Kent Ridge Road, Singapore 119083
Telephone: 67724989 extension 1788
Mobile: 91719755*

School Dental Service, HPB:

*Dr Lim Wanyi
School Dental Service
Health Promotion Board
Level 4, 3 Second Hospital Ave, Singapore 168937
Telephone: (65) 64353147
Mobile: 98340174*

for all research-related matters. In case of any injuries during the course of this study, you may contact the above contacts as well.

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research subject, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about the NHG Domain Specific Review Board at www.research.nhg.com.sg.

If you have any complaints or feedback about this research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

MAIN INFORMED CONSENT FORM

Protocol Title:

Regenerative Endodontic Therapy (RET) using Antibiotic pastes or Calcium Hydroxide disinfection for the management of immature non-vital permanent teeth in children: A Randomized Controlled Clinical Trial

Principal Investigators & Contact Details:

NUH Dental Centre:

Dr Tong Huei Jinn

*Discipline of Orthodontics and Paediatric Dentistry,
Faculty of Dentistry, National University of Singapore,
11 Kent Ridge Road, Singapore 119083
Telephone: 67724989 extension 1788
Mobile: 91719755*

School Dental Service, HPB:

Dr Lim Wanyi

School Dental Service

Health Promotion Board

Level 4, 3 Second Hospital Ave, Singapore 168937

Telephone: (65) 64353147

Mobile: 98340174

I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction.

By participating in this research study, I confirm that I have read, understood and consent to the (NUH or HPB) Data Protection Policy. I also consent to the use of my Personal Data for the purposes of engaging in related research arising in the future.

Name of Participant

Signature

Date

Legally Acceptable Representative (LAR) Information

Name of LAR

Signature

Date

Translator Information

The study has been explained to the participant / legally acceptable representative in _____ by _____

Impartial Witness Statement

I, the undersigned, certify to the best of my knowledge that the participant signing this informed consent form had the study fully explained in a language understood by him / her and clearly understands the nature, risks and benefits of his / her participation in the study.

Name of Impartial Witness

Signature

Date

Investigator Statement

I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of his/her participation in the study.

Name of Investigator/
Person administering consent

Signature

Date