



PARTICIPANT INFORMATION SHEET

Please read the following information carefully. Do not hesitate to discuss any questions you may have with your doctor.

Study Title

Clinical, Microbiological and Quality of Life outcomes following use of systemic and local antimicrobials in the management of Odontogenic Infections in paediatric patients.

Introduction

In children, infection of the teeth are usually due to deep cavities on teeth, gum problems, or trauma. The infection may spread into adjacent tissues and may result in pain, swelling with pus and difficulty in eating or drinking. Most infections are treatable by cleaning of the teeth and placement of suitable dressing or removal of the tooth or drainage of the pus with or without oral antibiotics. Infections of teeth with systemic involvement usually require hospitalization for further care.

What is the purpose of this study?

In this study, we will compare the effect of two types of dressing applied in the teeth (Odontopaste and Calcium hydroxide) and oral antibiotics in resolving infections of the teeth in children in terms of symptoms/signs, microbial count and oral health quality of life in a systematic manner. All three treatment options are routinely used but have not been compared in a systematic manner. Your child will receive either one of the three treatment options. A total of 120 subjects with infections of teeth will be invited to participate in this study.

What are the procedures to be followed?

When your child comes with an infection of the tooth, his/her suitability to join this study will be determined. Subsequently, your child's mouth will be checked for multiple parameters such as pain, swelling, temperature, etc. In addition, photographs and X-rays will be taken and you will be asked to fill up a questionnaire before treatment. Then, your child will be selected for one type of treatment randomly. The infected tooth will be cleaned using a dental drill and/or dental instruments. The root canals of the tooth will be opened and a sample of the bacteria will be taken for further test. After cleaning the tooth thoroughly, it will be dressed and closed with a filling material. Your child will need to attend for follow-up at day three and day five. On the third day, your child will be reviewed to monitor progress and photographs will be taken. Similarly, on the fifth day, along with clinical treatment followed by sample for bacteria and photographs, you will need to complete a questionnaire after treatment.

Who should not enter the study?

- If your child has taken antibiotics one month prior to their first visit to the department
- If your child has any systemic disease or medical condition
- If your child has cellulitis (spreading infection) which require hospitalization or immediate IV antibiotic treatment
- If your child's tooth is badly broken down and requires removal
- If your child has teeth with roots extensively resorbed ($> 2/3^{\text{rd}}$)
- If your child has upper respiratory tract infection
- If your child is a known case of allergic or resistance to amoxicillin

What will be the benefits of the study?**(a) To participant?**

- The infected tooth will be treated with the highest standard of care.
- An honorarium amounting to RM50 will be given on the third day and in addition to that, RM50 and a gift will be given as a token of appreciation on the fifth day.
- Your child is entitled to a comprehensive dental treatment at the Paediatric dental clinic at the Faculty of Dentistry, UM even after the completion of this study.

(b) To the investigator?

- To find the best treatment alternative for infected teeth in children.
- The outcomes obtained from this study will possibly aid in formulating guidelines for infected teeth in children.

What are the possible drawbacks/ risks / complications / adverse effects that may happen?

- In the event the treatment rendered is unsuccessful, any complications will be addressed accordingly.

Can I refuse to take part in the study?

Your participation is totally voluntary. You need not have to explain why you prefer not to take part in the study and it will not affect your child's dental treatment.

Who shall I contact if I have additional questions/complications during the course of the study?

Main and other investigators (all listed in the application form):

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CONSENT BY PARTICIPANT'S PARENT/GUARDIAN FOR RESEARCH
FACULTY OF DENTISTRY, UM, K.L.

I, Identity Card No. of
**(Name of participant's parent/guardian)*

.....hereby agree
(Address)
to allow my daughter/son named to take part in the
(Name of participant)
research specified below:

Title of Study: Clinical, microbiological and quality of life outcomes following use of systemic and local antimicrobials in the management of Odontogenic Infections in paediatric patients.

After knowing and understanding all the possible advantages and disadvantages of this research, I voluntarily consent of my own child to participate.

I understand that my child can withdraw from this research at any time.

Signature Date
**(Participant's parent/ guardian)*

IN THE PRESENCE OF

Name,

I/C No., Position

Signature Date
**(Witness for signature of participant's parent/ guardian)*

I confirm that I have explained to the *participant's parent/guardian the nature and purpose of the above mentioned research.

Signature Date
(Attending doctor)

* Delete where not applicable