INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

Buffered vs. Unbuffered Local Anesthesia in Mandibular Molars Diagnosed with Symptomatic Irreversible Pulpitis: A Controlled, Randomized, Double-blind Study

Protocol # 11447

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent and authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine whether one type of anesthetic (numbing medicine) will work better at numbing the nerve in a tooth than using a different type of anesthetic. A second purpose is to see if the time needed to numb the nerve in a tooth is different between the two anesthetics.

Both anesthetics are currently marketed (meaning your dentist uses them during standard of care procedures). This study is being done because while both are used regularly with root canal procedures, there has not been a study looking at whether one helps to better numb the nerve in the tooth in a short time period than the other.

We are asking you to be in this study because you are having a root canal procedure that requires anesthetic.

The study is being conducted by Dr. Ken Spolnik, and student researcher, Dr. Peter Alena, of the Indiana University School of Dentistry.

WHAT WILL HAPPEN DURING THE STUDY?

You will first be screened at your regularly scheduled appointment to determine if you qualify to be in the study (like reviewing your medical history and dental exam). The study procedures may be conducted at that same visit or at a second regularly scheduled dental visit. Regardless, the following steps will be performed as a part of the study procedures.

1) We will ask you some questions, such as your age and any previous reactions to anesthetics, to ensure you qualify to be in the study.

2) You will sign a treatment consent to consent to your standard of care root canal treatment. You will then sign this consent form to agree to participate in this study. The signing of the consent forms will take about 5-10 minutes each.
3) A trained research assistant will use a product assignment sheet to prepare the type of anesthetic formulation you have been randomly (like pulling from a hat) assigned to. This will take about 5-10 minutes.
4) The dentist will apply anesthetic directly to your gums to numb your gum tissue prior to the anesthetic injection. This standard of care procedure, which will be completed regardless of participation in this study, will take about one minute.
5) The student researcher will administer the anesthetic you have been assigned following manufacturer's directions (about 3 minutes) and begin timing how long it takes for you to get numb.
6) The student researcher will test the numbness you feel in the area to be treated until the test shows the nerve in your tooth is completely numb. This will be done by checking how long it takes for you to self-report that your lip, chin and tongue feel completely numb and a light rubbing of the tip of a dental instrument does not produce more feeling in these areas than a light pressure on your tissues. This will take a maximum of 10 minutes.
7) The dentist performing your root canal will perform the treatment procedure which may include testing of the tooth numbness and/or additional anesthetic to specific areas around the tooth being treated (these are standard of care procedures, performed regardless of your participation in the study). Once you are confirmed numb and the root canal treatment begins, your participation in this study will end.

If you participate in this study, we may learn things about you from the study procedures that could be important or interesting to you. Depending on the information, you might need to meet with professionals with expertise to help you decide what to do with the information. We do not have money or funds available to cover the costs of any follow-up consultations or actions. We will share any abnormal blood pressure or pulse oximetry data we may see during the dental procedure.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

There is one anesthetic medicine and one buffering agent used in the study. The anesthetic and buffering agent added to the anesthetic are marketed (can be bought by dental practices) and their use is considered standard of care in dental procedures involving root canals. Their use in this study is not anticipated to cause any increase risk to you beyond what is normal when used in a root canal procedure. Risks associated with anesthesia and the root canal treatment you will receive, will be covered in your treatment consent.

As with any dental procedure, there are risks of trauma or cross contamination. These risks are not considered a part of this study and will be covered in your treatment consent.

There is a risk of loss of confidentiality of study records as a part of this study. This risk will be reduced with the following procedures/protections:

1) Your study records will be identified with a study number, not your name. Documents such as this consent form which will contain your name will be stored in a separate, locked location that only study personnel can access.
2) Electronic study records will be stored in encrypted, password protected computer files that only study personnel can access.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

If you are injured as a result of participating in this study, you will be responsible for seeking medical care and for the expenses associated with any care received. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. No money or funds are set aside to pay for these types of injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled by signing this Informed Consent.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

We don't think you will have any personal benefits from taking part in this study, but we hope to learn things that will help others in the future.

WILL I BE PAID FOR PARTICIPATION?

You will not be paid for participating in this study.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study. However, participation in this study does not change your treatment costs.

HOW WILL MY INFORMATION BE USED?

The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. This may include making sure you meet the criteria to be in this study, gathering information about your medical history to include in the research data, reviewing results of your medical tests for safety purposes, or to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include your medical records. Those records may contain information related to your mental health, alcohol or substance abuse, HIV/AIDS, sexually transmitted diseases, and/or results of genetic testing.

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University School of Dentistry

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - The United States Food and Drug Administration (FDA)

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study contact the researcher, Dr. Ken Spolnik, at 317-274-5311
In the event of an emergency, you may contact the Graduate Endodontic Department at 317-541-4218.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT WANT TO PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and agree to participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual care or treatment or relationship with Indiana University.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Dr. Ken Spolnik at the Indiana University School of Dentistry, 1121 W. Michigan Street, Indianapolis, IN. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

The researchers may stop your participation in the study even if you do not want to stop if you are not cooperating or it is determined it is not safe for you to continue. Also, the researcher may withdraw your participation if you indicate you have no signs of any kind of numbness 10 minutes after the anesthetic was given. If this happens, you will receive additional anesthetic (as would be standard of care for a root canal procedure when the first anesthetic procedure did not take) but data for study purposes would no longer be recorded.

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

_____**Printed Name of Subject**

_____**Signature of Subject** _____ **Date**

_____ **Subject's Address (street, city, state, zip code)**