Title: A Comparison of Oral Sedation-related Events of Three Multiagent Oral Sedation Regimens in Pediatric Dental Patients

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LOMA LINDA UNIVERSITY
School of Dentistry

Informed Consent Agreement

Key Information for You to Consider
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation. • **Purpose**. The purpose of this research is to compare the incidence of adverse sedation related events between three different multi-agent oral sedation regimens in pediatric dental patients. • **Duration.** It is expected that your participation will last 12 months. • **Procedures and Activities.** You will be asked to complete two surveys after oral sedation session. The first will be after 8 hours and the second will be after 24 hours. Phone interview will be done at the provider convenience to collect the answers for the survey's questions. • **Risks.** Some of the foreseeable risks or discomforts of your participation include: Minimal risk. • **Benefits**. Some of the benefits that may be expected include: Provide pediatric dentists with data that assists them in their effort to minimize adverse events during sedation and use the least amount of medication, It will also assess the potential adverse effect over time among the three regimens. • **Alternatives.** As an alternative to participation, you could: Participation is voluntary, and the only alternative is to not participate.

Title: A comparison of oral sedation-related events for three multi-agent oral sedation regimens in pediatric dental patients.

Sponsor: The Center for Dental Research of Loma Linda University

Principal Investigator: Jung-Wei Chen, DDS, MS, PhD

Identification of Investigators

You are invited to participate in a research study conducted by Meena Adami, DDS, a graduate student in the department of Pediatric Dentistry at Loma Linda University (LLU). The research committee supporting this study includes Samah Omar, DDS, MSD, Laura McCormack, DDS, MSD. Assisting in this research is Mona Dousti, DDS, Vera Abhishek, DDS, Abhishek Batra, DDS. The use of your Protected Health Information is explained in the separate authorization form.

Contact Information

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Why is this study being done?

The purpose of this study is to compare three different commonly used oral sedation drug mixtures, to see which has fewer negative related events. In order to account for these events, the dentist performing the sedation will receive a survey regarding the period of time from administration of medications up until discharge. A list of questions will also be given to you concerning events that may occur during the 24 hours after sedation. You will be asked to complete two surveys after 8 and 24 hours and you receive a phone interviews regarding these questions after 24 hours.

How will I be involved?

Participation in this study involves the following:

- Participation in this study will require you to read and sign this informed consent document and take part in one telephone interviews.
- The questions asked will be concerning side effects that may take place up until 24 hours after sedation. This phone interview will take approximately 15 minutes for each call.
- The dentist performing the sedation will receive a survey regarding the period of time from administration of medications up until discharge.

What are the reasonably foreseeable risks or discomforts my child may have?

There are minimal risks to participating in this study. The oral sedation medications to be used are not experimental, are frequently used by a large variety of patients every day and would be used by the patient regardless of whether our research was being performed. Our goal is to document if there is a lower number of adverse events in one set of medications as opposed to the other. One risk of this survey is the chance that your private information could become public against your wishes. In order to protect your privacy, individual results of the survey will not be reported or published. The patients' names will not be noted on the individual surveys and will completely unknown to anyone involved in the survey process. As we will be unaware of your name or medical history, it will be impossible for this information to be accidentally released.

The results of this research will be presented at a public thesis defense. The researcher retains the right to use and publish non-identifiable data. Data will be presented as averages or generalizations about the responses as a whole. All data will be stored in a secure location accessible only to the researcher. All participants' responses will be destroyed 3 years following completion of the study.

Will there be any benefit to me or others?

There are no direct benefits to the participants in this study; however, the benefit of the research as a whole is to better understand the effects of three different multi agents' regimens, and to assist pediatric dentists with data in an effort to minimize adverse events during sedation.

What are my rights as a subject?
Your participation is entirely voluntary. Should you choose not to participate, you can withdraw at any time. Deciding not to be in the study or leaving the study before it is done will not affect your or your child's relationship with the researcher or with the health care provider.

What costs are involved?
There is no additional cost to you for participating in this particular study. If you have any questions about your insurance coverage or the items you might be required to pay for, please contact financial services for information, at 909-558-4689.

Will I be paid to participate in this study?
As the interviews are conducted by the researcher, each person who chooses to complete the surveys and the telephone interview will have their number noted onto a list. Participants on the list will have their numbers entered into a raffle to win one of six $100 gift cards. This raffle will be conducted by the form of a blind draw from a closed bag sometime after all 60 patients have been interviewed, which is estimated to be approximately May of the year 2020. A total of six gift cards will be given out, so that one out of ten people should receive a card. Applicants who only complete one of the two phone interviews will have their submissions withdrawn from the raffle. When the winning numbers have been selected the patient's parents will be informed and provided with the card.

Will study staff receive payment?

The Center for Dental Research is providing financial support for this study. This financial support includes hiring a translator to provide informed consent, survey questions, and telephone interviews when needed.

Who do I call if I have questions?

If you have questions you may contact Meena Adami at (909) 558-4689. The principal investigator of the project is Jung-Wei Chen, DDS and you may contact her at (909) 558-4690. If you wish to contact an impartial third party not associated with this study regarding any question or complaint you may have about the study you may contact the Office of Patient Relations at Loma Linda University Medical Center, Loma Linda, CA 92354 at (909) 558-4647. Email address: patientrelations@llu.edu.

Subject's Statement of Consent

- I have read this entire consent form and have listened to the verbal explanation given by the investigator.
- My questions concerning this study have been answered to my satisfaction. This protocol has been explained to my child at a level that he/she can comprehend, and I give permission for my child to participate in the study.
- Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities.
- I hereby give voluntary consent to participate in this study.

I understand I will be given a copy of this consent form after signing it.

_____ _____

Printed Name of Child Date

_____ _____

Printed Name of Parent/Guardian Signature of Parent/Guardian

Investigator's Statement

I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of the study.

_____ _____

Signature of Investigator Printed Name of Investigator

_____

Date