Universidad Austral de Chile
Conocimiento y Naturaleza

17/03/25

Participant Information Document and Informed Consent Form

This informed consent is addressed to patients attending the emergency departament of CESFAM Jorge Sabat de Valdivia, for extraction of maxillary and/or mandibular teeth with infiltrative techniques, who are invited to participate in the research **"Anesthetic Effectiveness in Dentistry of Lidocaine Versus Articaine. Randomized Clinical Trial."**

Natalia Curín Bachmann and Camila Henríquez Castro, dental students of the Universidad Austral de Chile, will carry out thus undergraduate tesis Project with the support of Juan Kunstmann, profesor Carla Bertrán.

"Anesthetic Effectiveness in Dentistry of Lidocaine Versus Articaine. Randomized Clinical Trial."

This document has two parts:

I) Information about the study.
II) Informed consent form to sign if you agree to participate.

You will be given a copy of the complete informed consent document.

Part I: Information

Introduction

We are Natalia Curín Bachman and Camila Henríquez Castro, dental students at Universidad Austral de Chile, in this document you are invited to participate in the study entitled **"Anesthetic effectiveness in dentistry of lidocaine versus articaine. Randomized clinical trial."**

Before deciding whether or not you want yo participate in the clinical trial, you will be given information about the project. You can take your time and discuss it with a family member or whomever you feel comfortable with. If you don't understand a word, you have the right to ask and the time to explain the procedure .

Purpose

Dental extractions are the most common procedures performed in emergency rooms, which is why anesthesia is essential to control pain during and after the extraction. For years the anesthetic lidocaine 2% has been the first choice for anesthesia, but ther are other options exist. The main reason for this study is to find out whether articaine 4% produces a better pain relief effect than lidocaine 2%.

Type of research intervention

This study consists of a clinical trial investigation, in which you will be given a buccal injection with one of the two anesthetics mentioned above at random, which can be lidocaine at 2% or articaine at 4%, both with epinephrine 1:100,000. A post-anestheia pain assessment will be performed using a Visual Analog Scale (VAS), a validated tool to estimate pain. It is a 10-centimeter line with numbers from 0 to 10, where 0 indicates no pain and 10 represents the most intense pain you have ever had in your life.

Selection of participants

We are inviting adult patients between 18 and 65 years old without systemic pathologies who are attended in the emergency room of CESFAM Dr. Jorge Sabat, Valdivia to participate in the research: "Anesthetic effectiveness in dentistry of lidocaine versus articaine. Randomized clinical trial."

Voluntary participation

Your participation in this research is completely voluntary. You may choose to participate or not. Whether you choose to participate or not, all the services you receive in this emergency room will continue, and nothing will change. You can change your mind later and stop participating even if you agreed before.

Information about the trial drug Articaine

The anesthetic we're using in this research is called articaine. It has been tested before on people to treat pain during tooth extractions. Now we want to test this anesthetic, but comparing it to the first choice anesthetic, which is lidocaine, to see if it has a superior benefit in reducing pain.
This stage of research is called "phase 4" of a trial.
The manufacturing laboratory of DFL articaine is of Brazilian origin, belonging to one of the largest companies in Latin America since 1939.
This anesthetic may have adverse effects in patients undr treatment with drugs that produce changes in blood pressure, tricyclic antidepressants or phenothiazines. Special caution in patients with hepatic or renal disorders. In patients with reduced cardiovascular function and in pregnant patients, during lactation and asthmatic patients, it should be administered under the supervision of a responsible profesional.
With respect to toxity it is similar to lidocaine.
Some of the research participants will not receive the anesthetic we are testing. Instead, they will receive lidocaine 2%, the most commonly used anesthetic for aneshtesia, although it has risks associated with the maximum dose, it is well tolerated and safe for the patient. Often this drug requires boosting.

Procedures and protocol

We need to compare the two anesthetics, because we don't know if the anesthetic to be investigation (articaine) is better than the one currently available for dental extractions (lidocaine). To do this, we will put the participants into two groups. The groups are selected by chance, just like flipping a coin. There is a 1 in 2 chance that you will get one anesthetic or the other.

Participants in one group will be given the test anesthetic under test (articaine), while participants in the other group will be given the drug currently in use for dental extractions (lidocaine). It is important that neither we nor you know which of the two anesthetics they are being given. This information will be in our files, but we will not look at these files untill the investigation is complete.

This is the best way fo rus to do a test without being influenced by what we think or expect to happen. Then we'll compare which of the two anesthetics gives better results.

Health care workers will be watching you and the other participants carefully during the study. If we become concerned about what the anesthetic does, we will find out which one you're getting and make changes. If there's anything that concerns you or bothers you about the research, please talk to me or one of the other investigators.

Description of the process

During the research there will be two interactions with the patient, at the same time he/she goes to the emergency room of the CESFAM Dr. Jorge Sabat Valdivia.

In the first interaction the researcher will ask each patient if he/she wants to participate in the experimental study. We will also ask about their age, general health, medication use, and allergies.

To assess pain, prior to the application of anesthesia, patients will be taught the Visual Analog Scale (VAS), a validated tool for estimating pain. It is a 10-centimeter line with numbers from 0 to 10, where 0 indicates that there is no pain and 10 indicates that the patient's pain is more intense.

Once the informed consent has been signed, the study is carried out.

The second interaction, which will be in the order of the waiting room, you will be given either the anesthetic under test or the one currently used in dental extractions.

As explained abovem neither you nor we will know which drug you have received, the one under test or the fake.

You will be given the visual analog scale previously taught at the time of the tooth extraction for pain measurement.

Duration

The investigation will last three months in total. During that time, it will not be necessary for you to come to the CESFAM Dr. Jorge Sabat of Valdivia. At the end of the three months, the research will be completed.

Side effects/Risks

As already mentioned, this anesthetic may have some adverse effects. But mainly if you are under treatment with drugs that produce changes in blood pressure, tricyclic antidepressants or phenothiazines. As well as in patients with hepatic or renal disorders, with reduced cardiovascular function or in pregnant patients, during lactation and asthmatics. As well as other risks associated with anesthetic techniques,

such as: hematoma, edema, transient parestesia, CNS overdose; dizziness, drowsiness, arrhythmias in case of toxity.
It's possible that it may also cause problems we're not aware of. However, we'll monitor and keep a record of any unwanted effects or any problems. We may use other medications to lessen the symptoms of side effects or reactions. Or we may stop using one or more of the anesthetics used. If this is necessary we will discuss it with you and you will always be consulted before proceeding to the next step. We will continuously monitoring your symptoms during the procedure to rule out complications.

Discomfort

When participating in this research, you may experience some discomfort in the sense of taking up a little more of your time to collecting your data.

Benefits

There are direct benefits to you for practicing in this research. However, if you participate in this study, you will not have to pay any costs associated with participating in the study.
In addition, your participation is likely to help us find an answer to the research question.

Incentives

We will send you the results of the completed study via email along with an invitation to an oral health awareness talk. No other money or gifts will be given to you for taking part in this research.

Confidentiality

We will not share the identify of those who participate in the research. The information we collect for this research project will be kept confidential. Information about you that is collected during the research will be kept confidential and no one except the researchers will have access to it at the end of study.
The information will be stored in a Google Drive cloud and will be maintained with periodic backups. Any information about you will have a code instead of your name. Your information will not be shared or given to anyone except the principal investigators as mentioned above at the end of the study.

Sharing the results

I is posible that this research may be published in a scientific journal or presented at scientific events. If so you will be informed through an appropriate mechanism where such publication will be made available. Please note that no confidential information will be shared.

Right to refuse or withdraw

You don't have to participate in this research if you don't wish to, and refusal to participate will not affect your treatment in this emergency room in any way. You will still receive all the benefits you would otherwise have at this Cesfam.
You may stop participating in the research at any time you wish without losing your rights as a patient. Your treatment at this location will not be affected in any way.

Alternatives to participation

If you do not wish to take part in the investigation, you will be provided with the standard treatment use available at CESFAM Dr. Jorge Sabat. Patients are usuallly given the anesthetic lidocaine 2% with epinephrine 1:100,000.

Who to contact

If you have any questions, you can ask them now or later, even after the study has started. If you'd like to ask questions later, you can contact any of the following people via email:

Natalia Curín Bachmann natalia.curin@alumnos.uach.cl
Camila Henriquez Castro camila.henriquez01@alumnos.uach.cl

This project has been reviewed and approved by the Scientific Ethics Committee of the Los Ríos Health Service. This committee is accredited and is function is to safeguarding the rights of people as reseach subjects. If you wish to find ouu more about this committee, please contact cecsslr@redsalud.gob.cl, call 632281784, or visit the Prales Building, Vicente Pérez Rosales 560, Office 307, 3rd Floor, Valdivia, Chile.

PART II: Consent Form

- **• I have been invited to participate in the research on the effectiveness of lidocaine and articaine for pain control in dental extractions with infiltrative techniques-**
- **• I understand that I will receive an anesthetic and a scale on which I must mark the pain that I perceive at the time indicated to me.**
- **I have been informed that there are unwanted effects, but they are unlikely.**
- **I know that there will be direct benefits to me beyond the delivery of the anesthetic free of charge.**
- **I hace been provided with the name of an investigator who can be easily contacted using the name and email/adress given to me of that person.**
- **I have read the information provided ori t has been read to me.**
- **I have had the opportunity to inquire about it and have had the questions I have asked answered to my satisfaction.**

_____ I consent

_____I do not consent

I have voluntarily decided to participate in this research as a participant and understand that I have the right to withdraw from the research at any time without affecting my medical care in any way.

Participant's name_____
Participant's RUT_____

Participant's signature_____

Date_____ **Day/month/year**