AULA DENTAL AVANZADA

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*ClinicalTrials.gov: NCT04395690*

**INFORMED CONSENT TO PARTICIPATE IN A CLINICAL TRIAL**

**Oficial title of the study:** Prospective Randomized Multicenter Study Between Two Anesthetic Techniques for Implant Placement in the Posterior Mandible

**Name of the Study Director:** Dres. Guillem Esteve Pardo, Ernesto De Larriva González y Lino Esteve Colomina.

**Name of the Dentist who performs the operation and date:**

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**Clinic where the study will take place:**

.....

A) **Information sheet:**

We are asking you to participate in a multicenter research study because you are a candidate for posterior mandibular implants. This type of study is done to be able to know more about the effect of the anesthetic technique and about the comfort of the patient during the treatment and thus be able to achieve a higher quality in the implant placement procedures.
Your participation is completely voluntary; if you do not wish to do so, your dentist will continue with your usual care and your refusal will not bring you any inconvenience.
Read all the information provided in this document and ask all the questions you need to your dentist who is explaining it to you, before making a decision.
Dr..... will carry out the intervention and Drs. Guillem Esteve Pardo, Ernesto De Larriva González and Lino Esteve Colomina will lead the investigation.
The dentists will not be paid extra for carrying out this investigation.

***REMEMBER THAT THE ANESTHETIC TECHNIQUES USED IN THIS STUDY ARE OF NORMAL USE AND EITHER IS INDICATED IN YOUR CASE.***

***1) Why is this study being conducted?***

The purpose of this research is to find out which anesthetic technique leads to greater patient comfort during the placement of dental implants in the jaw and whether the patient's perception and subjective experience with one technique or another is comparable.

***2) How many people will participate and from where will they be selected?***

It is planned to include 48 people treated in 8 dental clinics in Spain in the study.

***3) What is known about this study?***

Due to the different anesthetic techniques valid for the placement of implants in the posterior areas of the jaw, there is no consensus about which one causes less discomfort to the patient and allows a better anesthesia to perform the procedure. We intend to know with our study if one technique is superior or not to the other, in terms of comfort for the patient.

***4) What should I do if I agree to participate?***

- If you agree to participate in the study, you must sign this Informed Consent. You will then be asked a series of questions about your medical status to see if you have all the necessary conditions to be included.
- If you are included in the study, you must comply with the following instructions:
- - Answer the questions that the investigator will ask you at three different times during the implant placement procedure.
- - Go to the clinic 7 days after the intervention for the removal of the suture, and answer one more question.
- Inform the clinic of any problems that occur after the procedure.

***5) How long will I have to stay in the studio?***

Your participation is scheduled to last 7 days.

***6) Will all participants receive the same anesthetic administered with the same technique during the study?***

This study includes 2 groups of participants:

- Group 1 (24 patients): will receive 4% articaine with 1:100000 epinephrine administered with an infiltrative technique by vestibular and lingual.

- Group 2 (24 patients): will receive 4% articaine with 1:100000 epinephrine administered with a lower dental nerve trunk technique.

It will be decided at random (with a computer program) which group you will belong to and this will only be known by your dentist at the time of the intervention. This is done to obtain reliable data on the results of the study.

***7) What other anesthetic options do I have, if I decide not to participate in this research study?***

If you do not participate in the study, your dentist will use the anesthetic technique he or she considers for your case, which will be one of the two described above. Remember that these anesthetic administration techniques are those described for the placement of implants in posterior mandibular areas. We are not experimenting with you.

***7) What risks will I have if I participate in the study?***

The risks you will have if you participate are the same as if you do not participate, since the anaesthetic techniques are those normally used in cases that are usually intervened.

***8) Will I get benefits for participating?***

It is likely (though not certain) that you will benefit from the results of this study, as it may help us improve patient comfort in pre-mandibular implant anesthesia.

***9) Can I stop participating at any time, even after I have accepted?***

You are free to withdraw your consent to participate in the research at any time without prejudice to your subsequent dental care; you simply need to notify the researcher of your decision verbally. After withdrawal of your consent, no data about you and your health can be obtained but all previously obtained information can be used.

***10) Can I be removed from the study even if I don't want to?***

The investigator, the study directors and the ethics committee overseeing the study may decide to withdraw the study if they feel it does not meet the study's inclusion criteria. Similarly, if he does not appear at the second appointment after 7 days, his withdrawal from the study may be considered since relevant data for the continuation of the study are missing.

***11) Will I get paid for participating?***

You will not be paid for your participation in this study.

***12) Will you inform me if there are any developments during the study that might cause me to decide to stop participating?***

If during the study there is new information that may be important enough for you to want to stop participating, you will be informed as soon as possible.

***13) How will you maintain the confidentiality of my personal data? How will you ensure that my identity is not known?***

This document will become the property of the clinic where you are a patient and have allowed the handling of your personal data. These data will not be used for the study and the rest of the researchers, apart from your dentist, will not know your identity at any time.

**B) Informed Consent (Signature Sheet)**

I have received a satisfactory explanation of the study procedure, its purpose, risks, benefits and alternatives.

I have been satisfied with the information received, I have understood it, all my doubts have been answered and I understand that my participation is voluntary.

I give my consent for the proposed procedure and know my right to withdraw it whenever I wish, with the only obligation to inform the dentist responsible for the study of my decision.

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Signature, subject's national identity card number and date

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Signature, dentist's registration number and date