UNIVERSIDAD NACIONAL AUTÓNOMA DE MÉXICO

Master's and Doctorate Program in Science
Medical, Dental and Health

INFORMED CONSENT

Randomized clinical trial of electrostimulation therapies with an electromyographic multifractal analysis device for patients with temporomandibular disorders

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NTC ID: Not yet assigned

ID: CIE/0508/02/2020

LETTER OF INFORMED CONSENT TO PARTICIPATE IN DENTAL RESEARCH STUDY

Project title: Randomized clinical test of electrostimulation therapies with Electromyographic multifractal analysis implement for patients with disorders temporomandibular.

Main researcher: Mtra. Claudia Ivonne Rodríguez Castañeda

Co-responsible researcher: Dr. Fernando Ángeles Medina

Headquarters where the study will be carried out: Laboratory of Oral Physiology, from the Division of Studies of Postgraduate and Research (DEPeI) of the Dentistry Faculty of UNAM.

You are being invited to participate in this research study. Before deciding to participate, you must know and understand each of the following sections. This process is known as informed consent. Ask your doubts about it. If you want to participate, I will ask you to sign this form, of which you will be receiving a copy.

JUSTIFICATION OF THE STUDY

Assess pain and do studies of the internal function of your face (muscles) every week, obtain this information will be useful to us to measure the improvement and thus enhance the treatment.

THE PURPOSE OF THE STUDY

Compare the changes in pain measurements and muscle function each week.

STUDY BENEFITS

Wearing an occlusal splint will produce a stable position of your teeth improving muscle function and articulate.

Electrical therapies decrease pain and tension in your muscles, improving your health.

STUDY PROCEDURES

If you agree to participate in the study, we will make a file for you. Treatment consists in the use of a device called a “splint” (day and night) and every week we will schedule an appointment for you to make adjustments to the device and measure the functioning of your muscles, this study it's called Electromyography.

In case your treatment includes electrical therapies, the therapies will be applied for medium of surface electrodes or needles. The application of therapy and method application will be determined randomly (randomly). You can only get one of the 3 types of treatment: 1) Use of splint and electrical therapy with electrodes, 2) Use of splint and electrical needle therapies and 3) Splint use only- Treatments have a duration of 6 weeks and appointments will be scheduled 1 time each week.

RISKS ASSOCIATED WITH THE STUDY

In accordance with the Regulations of the General Health Law on Health Research, this project is considered as Research with risk greater than the minimum.

ELECTROMYOGRAPHIC RECORDING PROCEDURE

To measure the function of your muscles you will be sitting in the dental chair, we will clean your face to place 3 electrodes on the skin of your right cheek and 3 on the left, the electrodes; these are to connect the device to your muscles by means of cables. After this, we will ask you to bite for 30 seconds while the computer records it. The study will be held in the Physiology Laboratory of DEPeI, UNAM.

ELECTRO-STIMULATION THERAPY

Electric therapy is recommended by the World Health Organization for pain relief produced by the disease you have.

It consists of the placement of two very small and thin needles or two electrodes in each cheek to which we will connect some cables to be able to stimulate the muscles for 20 minutes. **This therapy does not cause pain** you will only feel small pulsations. Therapies will be done once every week in the Physiology Laboratory of DEPeI, UNAM.

RECOMMENDATIONS TO FOLLOW FOR THE USE OF THE SPLINT:

You will need to wear it 24 hours a day and only need to take it off to eat and brush your teeth.

The appliance should be washed twice a day (morning and evening) with liquid hand soap and rubbing it with your fingers, DO NOT scrub it with the brush because it scratches.

CLARIFICATIONS

- The decision that you participate in the study is completely voluntary.
- There will be no unfavorable consequence for you if you do not accept.
- If you decide to participate in the study, you can withdraw at any time you want.
- You will not have to spend any money to participate in the study.
- During the study you may request information that you require.
- The information of each patient will be kept strictly confidential by the group of researchers, so your name will be replaced by a pholio number.
- You will not develop any side effects from participating in this study.
- Through the review procedure if you have a problem, you will be told the diagnosis.
- Participation in this project does not imply the provision of free dental service or support for comprehensive dental treatment.
- If you consider that there are no doubts or questions about your participation, you can, if you wish sign the Letter of **Informed Consent** attached to this document.

If you have any questions related to the procedure of this study, you can communicate with:

Co-responsible Researcher: Dr. Fernando Ángeles Medina Tel: 5556225561

PLEASE KEEP THIS SHEET

I_____have read and understood the above information and my questions have been answered in a satisfactory. I have been informed and understand that the data obtained in the study. They can be published or disseminated for scientific purposes. I agree to participate in this research study.

I received a signed and dated copy of this consent form.

Name	**Signature**	**Date**
Address	**Mobile**	**Phone number**
Name of witness 1	**Signature**	**Date**
Name of witness 2	**Signature**	**Date**

This part must be completed by the Investigator:

I have explained to Mr(s)._____the nature and purposes of the investigation; I have explained about the risks and benefits that their participation implies. I have answered the questions to the extent possible and I have asked if you have any questions. I accept that I have read and know the corresponding regulations for conducting research with human beings and attachment to her. Once the question and answer session was over, we proceeded to sign this document.

Researcher's signature	**Date**

Researcher Sheet

I_____have read and understood the above information and my questions have been answered in a satisfactory. I have been informed and understand that the data obtained in the study. They can be published or disseminated for scientific purposes. I agree to participate in this research study.

I received a signed and dated copy of this consent form.

Name	**Signature**	**Date**
Address	**Mobile**	**Phone number**
Name of witness 1	**Signature**	**Date**
Name of witness 2	**Signature**	**Date**

This part must be completed by the Investigator:

I have explained to Mr(s)._____the nature and purposes of the investigation; I have explained about the risks and benefits that their participation implies. I have answered the questions to the extent possible and I have asked if you have any questions. I accept that I have read and know the corresponding regulations for conducting research with human beings and attachment to her. Once the question and answer session was over, we proceeded to sign this document.

Researcher's signature	**Date**

Patient Sheet

"LETTER OF REVOCATION OF CONSENT UNDER INFORMATION"

In case you no longer wish to continue participating in the study, please fill out the "LETTER OF REVOCATION OF CONSENT UNDER INFORMATION" and please forward it to the Research Project Staff.

Project title: Randomized clinical test of electrostimulation therapies with Electromyographic multifractal analysis implement for patients with disorders temporomandibular.

Main researcher: **Claudia Ivonne Rodríguez Castañeda**

Co-responsible researcher: **Dr. Fernando Ángeles Medina**

Venue where the study will take place: **Laboratory of Physiology of the Studies Division of Postgraduate and Research (DEPel) of the Faculty of Dentistry, UNAM.**

I_____through this channel I wish to inform my decision to withdraw from this research.

_____	_____	_____
Name	**Signature**	**Date**
_____	_____	_____
Address	**Mobile**	**Phone number**
_____		_____
Name and signature of witness 1		**Date**

Relationship with the participant: _____

_____	_____
Address	**Phone number**
_____	_____
Name and signature of witness 2	**Date**

Relationship with the participant: _____

_____	_____
Address	**Phone number**