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INFORMAÇÃO AO DOENTE

Comparison of Temporomandibular Joint Arthrocentesis With Infiltration of platelet-rich plasma (PRP) + Ropivacaine Versus PRP: Does It Reduce Postoperative Pain?

Aim of the study

This study aims to investigate the potential pain reduction by comparing a treatment group with additional ropivacaine and a control group without ropivacaine in the postoperative week in patients undergoing double-portal temporomandibular joint (TMJ) arthrocentesis with flushing and supplementation with platelet-rich plasma (PRP).

Description and Methods of the Study

A sample of 30 subjects with temporomandibular dysfunction and indication for TMJ arthrocentesis will be selected to participate in this study. Subject eligibility is determined according to the following criteria before study entry:

- In the opinion of the investigator, the subject can understand and comprehend the study in question;
- The subject signs the written informed consent form and provides the necessary privacy consent before the start of any study procedures;
- Patients with TMJ dysfunction with an indication for arthrocentesis;
- Male and female subjects between the ages of 18-99 years;
- For women of reproductive potential: use highly effective contraception for at least one month before the first visit and agree to use such a method during participation in the study.

Any subject who meets the following criteria will not be eligible for the study:

- The subject has had other previous minimally invasive or invasive treatments for temporomandibular disease;
- Subject has any contraindication to the use of ropivacaine according to the Ropivacaine (Fresenius Kabi) package insert;
- Subject has a history of allergy to any drug in the study;
- The subject taking analgesic medication before treatment for other conditions;
- The subject cannot interpret pain scales or read and interpret the study's target questionnaire;
- Women who are pregnant or breastfeeding. For women of reproductive potential, use of highly effective contraception for at least one month before the first visit is required (Combined oral contraceptive pill, vaginal ring, male and female condom, intrauterine device, diaphragm,

injectable hormonal contraceptive) and agreement to use such a method during study participation.

- Minors under the age of 18 and over the age of 60 may not participate in the study.
- Subjects diagnosed with the following conditions cannot participate in the study: cardiovascular disorders, peripheral vascular disease, arrhythmias, auriculoventricular conduction disorders, heart failure, hypotension, epileptic patients, patients with liver and kidney disease, patients with porphyria, patients with acidosis. Patients will be randomly assigned to either the ropivacaine treatment group or the control group in a blinded fashion. In the control group, patients will not be injected with ropivacaine. After treatment, the patients will answer a brief pain assessment questionnaire for seven days daily. After one week, they will be clinically reassessed by the investigator in charge. The information obtained is subject to medical confidentiality and will not be disclosed to anyone outside the study, nor will any personal data of the patient be disclosed.

Number of Participants and duration of the study

It is planned to participate thirty individuals in this clinical trial. The study will last seven days for each patient and run for twelve months.

Participant's obligations

The participant declares that they have made truthful statements regarding the diagnosis in their medical evaluation. The participant must follow medical advice during the seven days of the study, including any post-treatment dietary and recovery care that the physician recommends. By agreeing to participate in the study, the participant agrees to answer the questionnaire for seven days after the arthrocentesis has been performed.

Predictable Risks

No significant risks are anticipated. Information regarding individual participants is subject to medical confidentiality. The inclusion of ropivacaine in PRP injection has minimal risks associated with the systemic application, which does not apply to this trial, being a local administration. The chances are previously described in its descriptive package insert: "Important side effects to be careful about:

Sudden life-threatening allergic reactions (such as anaphylaxis) are rare and affect 1 to 10 patients per 10,000. Possible symptoms include sudden onset of skin rash (hives), itching, swelling of the face, lips, tongue or other body parts, shortness of breath, wheezing or difficulty breathing. Other possible side effects:

<u>Very common</u> (affects more than 1 in 10 patients):

- Decreased blood pressure (hypotension). You may feel dizzy or have a lightheaded feeling.
- Feeling unwell (nausea).

<u>Frequent</u> (affect 1 to 10 patients per 100):

- Tingling.
- Feeling dizzy.
- Headache.
- Fast or slow heartbeat (tachycardia, bradycardia).
- Increased blood pressure (hypertension).
- Feeling sick (vomiting).
- Difficulty urinating.
- Increased body temperature (fever) or stiffness (chills).
- Back pain.

Infrequent (affect 1 to 10 patients per 1000):
- Anxiety.
- Decreased skin sensitivity or sensitivity to touch.
- Fainting.
- Difficulty breathing.
- Low body temperature (hypothermia).
- Some symptoms may occur if the injection is mistakenly given into a blood vessel or if more ropivacaine is given than it should be. These include spasms (seizures), feeling dizzy or empty-headed, numbness of the lips and in the area around the mouth, numbness of the tongue, hearing problems, problems with your eyesight (vision), speech problems, muscle twitching, and tremor.

Rare (affect 1 to 10 patients per 10,000):
- Heart attack (cardiac arrest).
- Irregular heartbeat (arrhythmias).

Other possible side effects include:
- Numbness due to nerve irritation caused by the needle or injection. It usually does not last long.

Possible Benefits for Participants

Study participants will not receive any financial benefits that may result from this research.
For this study, the Portuguese Face Institute is covered by liability insurance under policy 008410178733.

Possible Benefits for Researchers and Research Center

Financial benefits are not foreseen for the researchers and research centre.

Voluntary Participation and Rights of Refusal or Withdrawal

You will be free to refuse to participate in the study, withdraw your consent, and stop participating at any time. Participation is voluntary, and your refusal will not involve any penalty or loss of

benefits. Furthermore, denial or withdrawal will not jeopardise your right to receive medical treatment or care, now or in the future, at this or another institution.

Study Participant Discontinuation

The investigator may discontinue or withdraw a participant from the study for the following reasons:

- Pregnancy/lactation
- Significant non-compliance with the study intervention
- If any clinical adverse effect, laboratory abnormality or other medical condition occurs such that continued participation in the study is not in the best interest of the participant
- Disease progression requiring discontinuation of the trial intervention
- If the participant meets an exclusion criterion (newly developed or not previously recognised) that precludes trial participation

Confidentiality

Information about each participant will be collected and analysed as part of this study. This information may be collected and combined with data from other participants. The investigator will store all potentially identifying information in the clinical or research file and will be kept confidential. Identification of the study participant will be made with a set of numbers and letters. This information may be reviewed by persons or entities authorised by the investigator and, in some instances, by the Ethics Committee, Health Authorities, under the supervision of the treating physician, to confirm the study data's veracity. In addition, information that does not identify the patient will be collected during the study and stored in a database and may become part of the published results. The data will be held for 20 years after the end of the clinical trial. The competent authority will require written authorisation for access to these data. The participant's name will not be identified in any report or publication from this study. This data may also form part of future research projects and be communicated to Regulatory Authorities. In addition, data may be accessed by external auditors and monitors of competent and accredited bodies.

Authorities that approved the study

This study was approved by the Ethics Committee of the Instituto Português da Face (IPFace).

Funding Sources

This study will have no funding source.

Research Team Responsible for the Preparation of the Study

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A physician with exclusive clinical dedication to orofacial pain and temporomandibular dysfunction at the Instituto Português da Face.

Invited Assistant Professor at the Faculty of Medicine, University of Lisbon.

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DECLARATION OF INFORMED CONSENT

(for clinical data collection)

Comparison of Temporomandibular Joint Arthrocentesis With Infiltration of platelet-rich plasma (PRP) + Ropivacaine Versus PRP: Does It Reduce Postoperative Pain?

INVESTIGADOR: Professor David Ângelo (MD, PhD)

HOSPITAL: Instituto Português da Face

PATIENT'S NAME: _____

PATIENT STUDY NUMBER:_____

I, , declare that I am aware of and agree to participate in a clinical study to evaluate the potential pain reduction by comparing a treatment group with additional ropivacaine and a control group without ropivacaine in the postoperative week in patients undergoing double-portal arthrocentesis of the temporomandibular joint (TMJ) with flushing and supplementation with platelet-rich plasma (PRP). I agree that my clinical data will be used by the precepts above.

The proposed study has been clearly explained to me. I have been allowed to ask questions. Accordingly, I declare that I agree to participate voluntarily in this study. I have received a copy of this informed consent statement, duly signed and dated.

Date:

Participant's signature:

In case the participant cannot read or write the Signature of an Impartial witness:

I have discussed this research study with the participant using understandable and appropriate language. I have adequately informed the participant about the nature of this study and its possible benefits and risks, and I believe that the participant has understood my explanation.

Date:

Doctor's name :

Doctor's signature: