TECHNICAL PRODUCT

Guidelines for future studies

Based on the results in the present study and due to the low certainty of the evidence on the use of botulinum toxin (TXB-A) for temporomandibular pain, we recommend that some guidelines be adopted for the conduct of new studies and that they may or may not corroborate for our findings. For this, it is necessary that the methodology is well described according to the CONSORT guidelines.

Criteria for a Randomized Clinical Trial (RCT)

The participants selection must be carried out at random for both groups, intervention and placebo, according to the protocol and prior research planning.

- Clinical trials can compare a new therapeutic approach to a standard of treatment already available, to a placebo (inactive treatment), or to no intervention.

- RCTs are indicated when a new approach or type of treatment is being studied, and it is not clear whether it will be useful, harmful, or not different from the available alternatives (including no intervention).

- Researchers should try to determine the safety and effectiveness of the intervention by measuring the results in the participants.

Randomized Clinical Trial Suggestion

Study type: Randomized controlled trials (RCTs) parallel design

Types of participants: Adults (over 18 years of age), of both sexes, with clinical diagnosis of temporomandibular disorder (TMD) of muscle origin, according to criteria such as the Diagnostic Research Criteria for Temporomandibular Disorders (RDC / TMD - Research Diagnostic Criteria for Temporomandibular Disorders) or the American Association of Orofacial Pain (AAOP) recommendations.

Exclusion Criteria: Pregnant and lactating women, under 18 years of age, patients with subluxation, central or neuropathic disorder that affects the masticatory muscles, myofascial pain of the cervical and / or fibromyalgia.

Future high quality randomized controlled trials are needed. These studies should follow:

- CONSORT Recommendations (Consolidated Standards of Reporting Trials);
- Study planning and protocol;
- Approval of the Ethics Code and Research for involving human beings;
- Definition of the research location;

• Definition of the sample size (approximately 200 participants in each group), considering that losses and the lack of adequate reporting of losses can compromise the quality of the results, due to the risk of bias;

• Generation of randomization sequence by appropriate methods (specific computer programs);

• Adequate allocation concealment (use of opaque and sealed envelopes);

• Blinding of participants, staff and outcome assessors;

• Adequate training of the team to deliver the injections;

• Detailed methodology for proper execution;

• Report of each stage of the study according to the study planning and protocol;

• Standardization of clinical parameters:

Clinical Parameters

Application groups: Group I - TXB-A versus Group II - Placebo (saline);

Application muscles: Masseter and Temporal bilaterally;

TXB-A dilution: The dilution must follow the dry dilution parameters, that is, each 100U of TXB-A for 1 ml of sterile 0.9% sodium chloride solution.

Dosage: 40 U in the masseter muscle on each side and 20 U in the temporalis on each side;

Application: every 3 months for one to two years.

Follow-up time: 1 month short term, 6 months medium term and 12 months long term.

Objetive

The objective of this study is to evaluate the effectiveness and safety of using TXB-A for the treatment of muscle temporomandibular pain according to pre-established parameters. The structured question was based on the following:

P (population) = adults with TMD of muscular origin;

I (intervention) = botulinum toxin type A

C (control) = placebo

O ("outcomes") = pain intensity, serious adverse events, any adverse event, quality of life.

Types of proposed outcomes

Primary outcomes

• Pain intensity, assessed using validated scales such as, for example, the Visual Analogue Scale (VAS), among others;

• Quality of life, assessed using validated questionnaires such as the SF-36, among others;

• Serious adverse events, measured with the proportion of participants who suffered at least one adverse event (for example, infection, dysphagia, among others);

• Any adverse event, measured with the proportion of participants who suffered at least one adverse event (for example, fatigue when chewing, muscle paralysis, aesthetic changes, allergy, headache, among others).

Secondary outcomes

• Function, assessed by validated questionnaires such as the Questionnaire and Mandibular Functional Limitation Index (MFIQ), the Cranio-Mandibular Clinical Dysfunction Index (IDCCM or Helkimo Index), among others;

• Use of analgesic medication, measured by the amount (or dosage) of pills taken daily.

Implications

- Adequate training and supervision of the team for punctual application to the muscles that will receive injections in the TXB-A or placebo groups;

- Registration of the study protocol in a registry base (example, Clinicaltrials.gov, Current Controlled Trials, among others).

- Report of the study according to the pre-established criteria (CONSORT - Consolidated Standards of Reporting Trials).