Pregabalin gel in reducing post-operative tooth sensitivity surgery caused by bleaching with 35% hydrogen peroxide

Sponsor(s): Universidade Federal do Para

Recruitment: upcoming  Participating centers 1  Last modification: 2023-12-24

STUDY DESCRIPTION

Even with a large number of agents with action desensitizing agents (which reduce the symptoms of tooth sensitivity) available in market, there is no treatment considered the gold standard, which is completely effective for treat sensitivity caused by tooth whitening treatment. In this sense, the Pregabalin (PG), a medication with analgesic and anti-inflammatory action, can be a effective alternative to control this discomfort.

Therefore, the objective of this project is to evaluate the effect of applying a gel containing the 10% Pregabalin associated with in-office teeth whitening, in reducing sensitivity dental.

Obtaining experimental pregabalin gel Pregabalin gel (PG) was obtained using a 1% carbopol gel base (carbopol 940, methylparaben, propylparaben, Ethylenediamine tetraacetic acid (EDTA), propylene glycol, 50% triethanolamine and distilled water) to which a solution of 10mg/ml of pregabalin. Obtaining a transparent, clear and consistent gel.

This pharmaceutical form was obtained from the Pharmaceutical Nanotechnology Laboratory of the Federal University of Pará and underwent characterization studies (FTIR, thermal analyses), study of rheological and stability properties (preliminary and accelerated), in addition to cytotoxicity assessment. Furthermore, a previous study for in vitro evaluation of the pregabalin gel associated with tooth whitening on dental enamel has also been carried out. It is noteworthy that satisfactory results were obtained, which make it safe for clinical application.

Sample calculation To define the sample size, a pilot study will be carried out (statistical power of 80% and an error probability α of 5%).

Sample selection Participants aged 18 to 40 of both sexes, with good oral health, will be selected. Individuals with active caries or periodontal disease, visible cracks in upper or lower anterior teeth, with evident malocclusion, restorations and prosthetics in anterior teeth, severe internal discoloration of the tooth (tetracycline, fluorosis or pulped teeth) are excluded. dentine exposure in anterior and/or posterior teeth, parafuncional habits, tooth sensitivity, whitening treatment prior to or undergoing orthodontic treatment. Furthermore, smokers, pregnant or breastfeeding women will not be included. Finally, participants must have at least 28 teeth in the oral cavity.

All participants will undergo prophylaxis carried out with a rubber cup and pumice stone seven days before the start of the clinical trial and will receive hygiene kits, with a toothpaste without desensitizing action and without fluoride, in order to mitigate possible interference in the evaluation of the results. The kit will consist of a toothbrush (Oral B, Ropes Indicator, São Paulo (SP), Brazil) and a toothpaste (My First Colgate®, Colgate Company, Sao Paulo, Brazil), with instructions for use three times a day.

Randomization and Blinding One of the study researchers, who will not participate in the clinical intervention stages, will be responsible for randomizing the sample. Randomization will be stratified and paired randomization, where participants will first be stratified according to gender (female/male). In this study, a double-blind model will be used, in which the participants and the researcher responsible for the clinical intervention will not know which treatment group the volunteer will be allocated to. Both products (placebo gel, experimental gel and commercial gel) will be placed in identical containers, corresponding to each group. Only the third research investigator involved in the randomization process will know the groups corresponding to each package. It is worth mentioning that all gels used in this study have similar color and consistency.

Study design Participants will be allocated into three different groups: GKF (5% potassium nitrate and 2% sodium fluoride (KF) - Desensibilize KF 2%, FGM, Brazil), GPG (pregabalin experimental gel) and GP (placebo). For the distribution of participants, a randomization process will be carried out.

In each group, the corresponding desensitizing gel will be applied to the buccal surfaces of the central and lateral incisors, canines and upper and lower premolars, with a microbrush actively, for 10 minutes. Subsequently, all groups will undergo in-office whitening treatment with 35% hydrogen peroxide (HP) (Whiteness HP, FGM). Sensitivity assessment will be carried out using a form consisting of a visual analogue scale (VAS), patients will be instructed to record tooth sensitivity daily during the 21 days of follow-up. To measure color, the VITA Easyscale spectrophotometer (VITA, Germany) will be used at two times: baseline (T1) and one week after the 3rd bleaching session (Tf).

Clinical protocol Tooth whitening After desensitizing therapy, gingival isolation will be performed with light-cured resin (Top Dam, FGM), for subsequent application of a whitening gel with a concentration of 35% hydrogen peroxide (Whiteness HP, FGM). According to the manufacturer's guidelines, three 15-minute applications of the whitening gel will be carried out on the buccal surface of the incisors, canines and premolars of the upper and lower arches, totaling 45 minutes in each of the whitening sessions. The whitening treatment will be carried out in three sessions, with seven day intervals between them.

Assessment of postoperative sensitivity To assess postoperative sensitivity, patients will be instructed to fill out a form to record tooth sensitivity daily, during the 21 days of treatment, based on individual pain perception. Patients will be instructed in detail on how to fill in the necessary information. The evaluation form will consist of the visual analogue scale (VAS). This scale consists of a 10 cm horizontal line, with scores of 0 and 10 at its ends, where 0 means no sensitivity and 10 means severe tooth sensitivity. The patient will be instructed to draw a vertical line along the horizontal line of the scale, recording the intensity of tooth sensitivity per day.
So that the distance in millimeters from the zero end can be later measured with the aid of a millimeter ruler, thus obtaining the patient's level of pain intensity.

Color evaluation The same researcher responsible for the clinical intervention will carry out the color assessment at two times: baseline (Ti) and one week after the 3rd whitening session (Tf). For this, the VITA Easyshade spectrophotometer (VITA, Germany) will be used, where the middle third of the buccal surface of the upper canines will be the standard assessment area.

To standardize color readings, silicone molds will be made, with canine-to-canine printing. A window will be created on the buccal surface of each canine of the silicone guide using a metallic device with a radius of 6 mm, corresponding to the diameter of the spectrophotometer tip. This way, the tip of the device will be inserted into the silicone guide to obtain the color parameters of the CIEL*a*b* system, where L* represents the value (light or dark); a* is a measure of red (positive a*) or green (negative a*); b* is a measure of yellow (positive b*) or blue (negative b*). The sum of the measured values of the upper canines will be used to obtain the averages for each L*a*b* coordinate for each patient. ΔL*, Δa* and Δb* will be calculated by the difference between the time intervals.

Subsequently, the color difference between baseline (Ti) and one week after the 3rd whitening session (Tf) will be calculated using the CIEDE2000 formulas (ΔE00).

Statistical analysis The sensitivity values reported by the volunteers will be tabulated in an Excel spreadsheet (Microsoft Windows 2010) and analyzed using the Jamovi software (Jamovi - Stats. Open. Now, version 2.2.5.0). The normality pattern of the tooth sensitivity and color data set will be verified using the Shapiro-Wilk test. If the sample has an abnormal distribution, the Friedman test will be used to evaluate different follow-up times in the same group (intragroup), and the Mann-Whitney test will be used for comparison between groups (intergroup). If it has a normal distribution, 1-way ANOVA (intergroup) and Tukey test (intragroup) will be used.

For color analysis, the Student's T test will be used. All analyzes will consider a significance level of 5%.

RECRUITMENT

Participant profile

- All

Medical condition (targeted specialty)

Research domain
- Tooth Bleaching
- Sensitivity, Tooth

Selection criteria

Inclusion Criteria:
Participants must have at least 28 teeth in the cavity
good oral and general health

Exclusion Criteria:
active caries or periodontal disease
visible cracks in front teeth upper or lower
with evident malocclusion
restorations and prosthetics in teeth anterior teeth
gastroesophageal disorders
severe internal tooth discoloration (tetracycline , fluorosis or pulped teeth)
dentin exposure in anterior teeth and /or later
parafuncional habits
tooth sensitivity
whitening treatment prior to or undergoing orthodontic treatment
Furthermore, smokers, pregnant or breastfeeding women do not will be included.

Cohorts

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<th>Name</th>
<th>Medical condition</th>
<th>Treatment</th>
<th>Recruitment status</th>
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The experimental 10% pregabalin gel (GPG) will be applied to the buccal surfaces of the central and lateral incisors, canines and upper and lower premolars, with an active microbrush, for 10 minutes. Subsequently, all groups will undergo in-office whitening treatment with 35% hydrogen peroxide (Whiteness HP, FGM). Sensitivity assessment will be carried out using a form consisting of a visual analogue scale (VAS), patients will be instructed to record tooth sensitivity daily, during the 21 days of follow-up. To measure color, the VITA Easyshade spectrophotometer (VITA, Germany) will be used at two times: baseline (Ti) and one week after the 3rd bleaching session (Tf).

The gel with 5% potassium nitrate and 2% sodium fluoride (NKFG) will be applied to the buccal surfaces of the central and lateral incisors, canines and upper and lower premolars, with a microbrush actively, for 10 minutes. Subsequently, all groups will undergo in-office whitening treatment with 35% hydrogen peroxide (Whiteness HP, FGM). Sensitivity assessment will be carried out using a form consisting of a visual analogue scale (VAS), patients will be instructed to record tooth sensitivity daily, during the 21 days of follow-up. To measure color, the VITA Easyshade spectrophotometer (VITA, Germany) will be used at two times: baseline (Ti) and one week after the 3rd bleaching session (Tf).

The placebo gel (PG) will be applied to the buccal surfaces of the central and lateral incisors, canines and upper and lower premolars, with a microbrush actively, for 10 minutes. Subsequently, all groups will undergo in-office whitening treatment with 35% hydrogen peroxide (Whiteness HP, FGM). Sensitivity assessment will be carried out using a form consisting of a visual analogue scale (VAS), patients will be instructed to record tooth sensitivity daily, during the 21 days of follow-up. To measure color, the VITA Easyshade spectrophotometer (VITA, Germany) will be used at two times: baseline (Ti) and one week after the 3rd bleaching session (Tf).

**LOCATIONS AND CONTACTS**

**Main location**

FEDERAL UNIVERSITY OF PARÁ SCHOOL OF DENTISTRY

BELEM, PARÁ

Local recruitment: UPCOMING

Date: 02/08/2024 22:06:30