Prospective randomized multicenter study between two anesthetic techniques for implant placement in the posterior mandible.

Protocol ID: ADA-1

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Study design

The null hypothesis of this comparative randomized clinical trial is that the intervention with either type of anesthesia is equally perceived by the patient.

Forty-eight patients needing implant placement in the posterior mandible, were enrolled in this prospective study, by eight different surgeons in eight different private dental centers with similar settings and socio-professional characteristics, following the same operating protocol, which had previously been thoroughly discussed among the participants.

All the patients were randomly included in one of the two groups: A (for interventions with IANB) and B (for interventions with INF) and assigned in equal proportions to surgeons. The "List Randomizer" (https://www.random.org/lists) was used as randomization method. When a participant surgeon had a patient to place implants in the posterior mandible, phoned to a person not participating in the study, to obtain the method of anesthesia to be used in this particular patient thirty minutes before intervention started.

The procedures were fully explained to the patients and all signed an informed consent for their voluntary participation in the study. The study was approved by the Ethic Committee of San Juan Hospital of the University Miguel Hernandez, Alicante, Spain.

The primary outcomes were pain perception by the patient during surgical procedure and patient's satisfaction 12 hours after operation. Data from patient's perceptions were collected using a Numerical Rating Scale (NRS) four times, three for pain perception (after incision, after drilling, after suturing) and one for global satisfaction (12 hours after operation).

Five confounding variables were also recorded: gender, the use of release incision, the number of implants placed, wether or not bone regeneration (GBR) was applied and the distance from the implant apex to the mandibular canal.

Statistical analysis

According to a previous calculation of the sample size, a minimum of 48 patients (24 per group) were determined to be necessary to reach a power of 75% with a Mann-Whitney test, a confidence level of 95% and a magnitude of 0.8 (strong) in pain level to be detected.

Data were tabulated to calculate descriptive statistics for all the variables of the investigation. Descriptive tables for the two primary variables were also tested by the five confounding variables. First, the homogeneity of two groups was verified. For the bivariate analysis, non-parametric tests were used:

- the chi-square and Fisher's exact tests were used as for groups homogeneity,
- the Mann-Whitney test to analyze the influence of the group on pain or satisfaction,
- the Spearman coefficient to measure the correlation between the two primary outcomes
- Friedman's test to check if the pain level was similar in incision, drilling and suturing.

For all tests, the significance level was set at 5% ($p < .05$).