CENTER FOR NEURO-
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COMPARATIVE STUDY OF THE EFFECTIVENESS OF HABITUAL THERAPY FOR PARKINSON'S DISEASE WITH PERMANENT AURICULAR ACUPUNCTURE AGAINST HABITUAL THERAPY WITHOUT ACUPUNCTURE

Health product: Forever Needle permanent needle, Model FOREVT80, Class IIb, GMDN (Global Medical Device Nomenclature) Code 12730 (Needles, Acupuncture), (SEDATELEC) (ISO 13485).

Clinical research plan: A comparative study of the efficacy of the usual therapy for Parkinson's disease plus permanent auricular acupuncture versus the usual therapy without acupuncture.

This clinical investigation was conducted in full compliance with the principles established in the "Declaration of Helsinki, 1996" (update of Seoul 2008). The clinical research fully complied with the principles established in the UNE - EN - ISO 14155 part 1, "Clinical investigation of medical devices for humans. Part 1: General Requirements ". In the clinical investigations with health products carried out in the EU / EEA countries, the researcher and the promoter ensure that the Council Directive 93/42 / EEC of 14.6.93 was complied with (DOCE nº L 169 of 12.7.93) , relating to medical devices (Article 15: Clinical Investigations, Annex VIII: Declaration regarding products that have a special purpose, Annex X: Clinical evaluation).

1. SUMMARY.

Title:
Comparative study of the efficacy of the usual therapy for Parkinson's disease plus permanent acupuncture versus the usual therapy without acupuncture.

Introduction:

This is a comparative clinical investigation of the effectiveness of the usual therapy for Parkinson's disease (PD) plus permanent acupuncture versus regular therapy without acupuncture. The clinical research has been evaluated by the Autonomic Committee for Clinical Studies of Medicines and Health Products of the Valencian Community (CAEC) and by the Spanish Agency for Medicines and Health Products (AEMPS).

Goals:
Its main objective is to compare the efficacy at 12 months of pharmacological treatment plus acupuncture with permanent needles versus pharmacological treatment without acupuncture, by its evaluation by a unified score scale for PD, the Unified Parkinson's Disease Rating Scale (UPDRS).

2. To evaluate the influence of variables on the proportion of patients with a reduction of ≥20% in the UPDRS to 12 months.

3. Follow the evolution of the pharmacological treatment received by each patient the first month (weekly), the second month (fortnightly) the third month (1 time), the four, eight and 12 months.

4. Evaluate safety by collecting and analyzing adverse effects (AEs) related to permanent atrial acupuncture therapy using MedDRA classification.

Subjects:
The population of clinical research is constituted by patients on pharmacological treatment for PE within the usual clinical practice. Such treatment will have been prescribed by their respective doctor or neurologist prior to entering clinical research.

Methods:
The procedure of the medical device: The insertion points of the permanent needles for the treatment of PD are selected individually. In addition to the implants in central points, which correspond to the main characteristics of the PD, implants are placed in other specific points depending on the condition and the symptoms of each patient.

Implantate between 100 and 120 needles, as many as the strength of the symptoms required, to achieve greater magnitude and consistency of benefits.

In the case of patients who receive the non-acupuncture process, the procedure will be identical to the patients who receive it, with the same number of Sham needles (from 100 to 120) but without any needle permanently penetrating the ears of the patient. patient, but that they are applied producing microperforations in the areas in which it would correspond depending on the suffering and the symptomatology of each patient.

Number of subjects:

• Recruited subjects: 47

• Randomized subjects: 42

• Subjects completed according to the clinical research plan: 32

• Subjects who voluntarily withdraw: 10

Relevant dates of the Clinical Investigation:
• Clinical research approval date: Nov 18, 11

• Start date of the clinical investigation (first subject included): Jan 25, 2013

• End date of the clinical investigation (finalization of the last subject treated): 21-Mar-16

Results:
The population required to find significant differences, considering 10% of dropouts, was 62 patients (31 per group). Finally, the number of patients recruited was 47, of which 42 were randomized. The number of patients who completed the clinical investigation according to the clinical research plan was 32.

The small number of patients did not allow the statistical analysis established to determine the statistical significance. Instead, descriptive variables are collected.

Conclusions:
Analyzing the descriptive of the variables, and comparing the results of the patients of the Needle Forever Needle group versus those of the Comparator group Sham needles, it can be concluded that:
• The efficacy of the Needle Forever Needles for the treatment of PD is not established in this clinical investigation.

• Needle Forever Needle, from now on "Needles", confer greater stability to the pharmacological treatment against PD because when comparing patients with needles vs. patients with Sham needles, these:

- They present an improvement regarding the complications in the treatment.
- They present less modifications in the treatment (reductions, increases, inclusion of new drugs).

Promoter:
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