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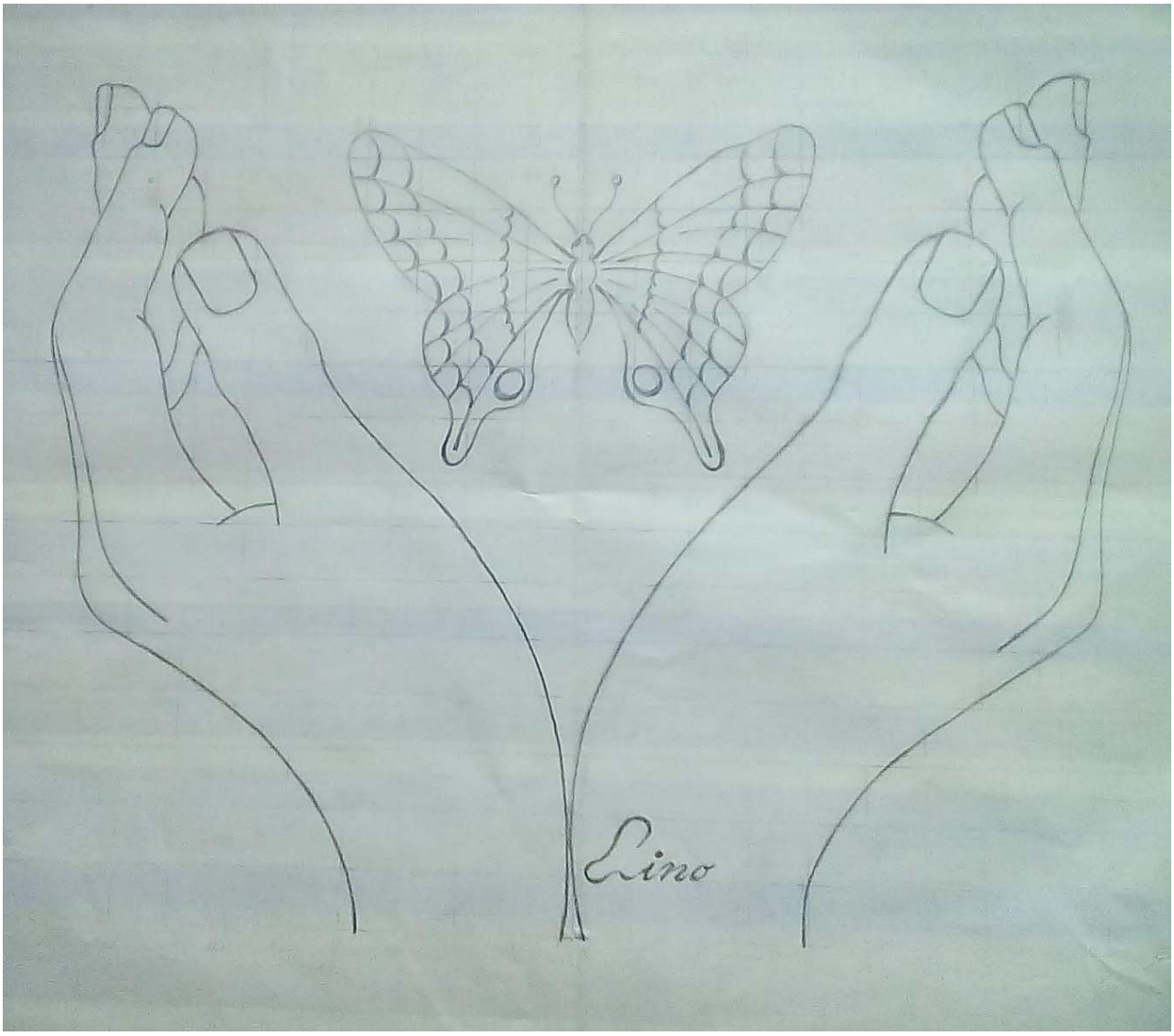

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SAFETY AND EFFECTIVENESS OF CIBIDES TIROSINT IN PATIENTS WITH CRHONIC PAIN: MEDICAL AND NURSING ASPECTS.

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KEY-WORDS: PAIN, THC, HRV, NEUROVEGETATIVE SYSTEM, NURSING APPROACH.

ABSTRACT

AIM: .The aim of our study is to evaluate the cardiovascular efficacy and safety of Cibides® in the treatment of chronic pain secondary to osteoarthritis. **MATERIALS and METHODS**: 16 subjects (10 M and 6 F) affected by chronic pain secondary to osteoarthritis were enrolled in our study. All enrolled subjects, over age 65.The patients enrolled had a minimum age of 74 years and a maximum age of 90 years (with an average age of 81.9 years with a standard deviation of +/- 7.987 years). All patients enrolled in the study provided informed consent for the processing of their personal data and the non-invasive recording of electrocardiographic and bioimpedance parameters. After obtaining consent, the enrolled patients underwent bioimpedance evaluation upstream and downstream of the application site of the Cibides® Lipogel and continuous electrocardiographic recording lasting 3 minutes or 250 beats with a 5-lead Medixai electrocardiograph for the Heart Rate Variability study. After data acquisition, an evaluation of the current pain was requested using a VAS scale with a range from 1 to 10 points (with 0 for minimum pain and 10 for maximum pain). At the end of the data recording, the Cibides® Lipogel cream was applied locally. Approximately 1 hour after applying the cream, the skin bioimpedance measurement and electrocardiographic recording were repeated. Pain assessment was carried out after 3 days of treatment in accordance with data published in international literature regarding the treatment of acute pain. **RESULTS:** the data relating to the pilot study carried out on 16 patients, treatment with Cibides® Lipogel determines a statistically significant reduction in pain assessed by VAS scale (7.875 + 0.806 vs 0.813 + 1.276 with $P < 0.001$) underline a statistically significant variation in the values of the skin resistance (68.813 + 20.666 vs 61.500 + 18.751 with $P < 0.001$)) and the locoregional skin reactance (12.063 + 7.767 vs 9.188 + 5.154 with $P < 0.004$) confirming the pharmacological action of cibides lipogel. No statistically significant variation was found in autonomic modulation assessed by dynamic electrocardiography. **DISCUSSION:** the data undeline that the treatment with Cibides® lipogel based on 0.02% THC allows the control of painful symptoms in chronic arthritic-based pain confirmed by statistically significant variations in the values of resistance and locoregional skin reactance evaluated after approximately 1 hour after applying the locole treatment. The absence of statistically significant variations in the orthosympathetic (AR-LF) and parasympathetic (AR-HF) neurovegetative parameters

confirms the safety of the treatment even in the most extreme age groups. **CONCLUSION**: treatment with THC extract-based Cibides® lipogel allows the perception of locoregional pain to be modulated, allowing optimal control of painful symptoms in chronic arthritic pain without determining statistically significant changes in orthosympathetic and parasympathetic modulation. The absence of statistically significant variations in the orthosympathetic and parasympathetic tone allow us to highlight the pharmacological safety even in the older age group. Since the data relate to a group of 16 patients of Italian nationality with an average age of 81.9 years, the pilot data of the present study are not applicable to all age groups of the population. **Limitation of the study:** the current size of the sample under examination is not sufficient to carry out a reliable evaluation that can be extended to the entire population.

Table

	BASE ± DS	**CONTROL ± DS**	**Probability (P)**
VAS (0-10)	7,875 +/- 0,806	0,813 +/- 1,276	< 0,001
RESISTENZA (Ω)	68,813 +/- 20,666	61,500 +/- 18,751	< 0,001
REATTANZA (Ω)	12,063 +/- 7,767	9,188 +/- 5,154	0,004
RR var (ms)	849,250 +/- 176,197	864,694 +/- 197,474	0,482
AR-LF (%)	59,0440 +/- 19,282	48,019 +/- 17,053	0,285
AR-HF (%)	34,975 +/- 21,753	37,238 +/- 21,504	0,680
AR LF/HF	3,587 +/- 4,732	3,161 +/- 5,660	0,813

Tab.1: Descriptive statistics of the changes in the parameters examined before and after treatment with Cibides Lipogel. Data are expressed as mean +/- SD.

Figure

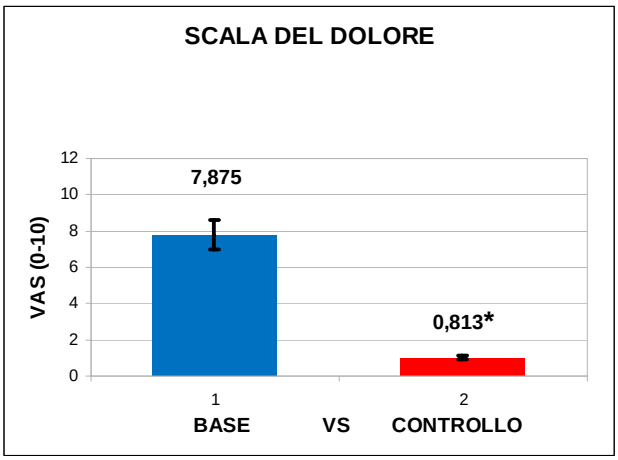

Fig. 1: Graphic representation of the changes in the score relating to the perception of chronic pain before and after treatment with Cibides Lipogel. Data are expressed as mean +/- SD.

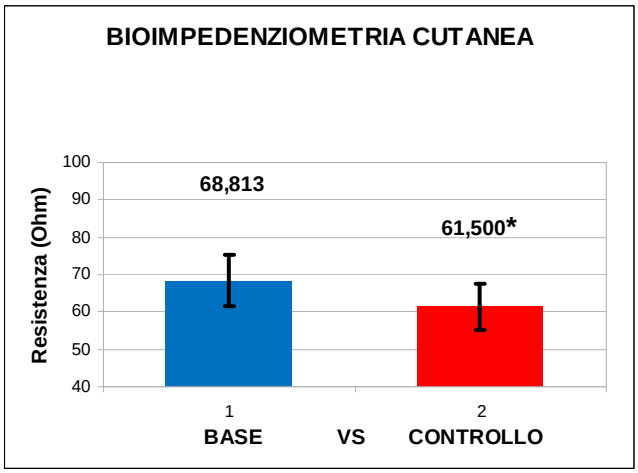

Fig. 2: Graphic representation of the changes in the resistance value before and after treatment with Cibides Lipogel. Data are expressed as mean +/- SD.

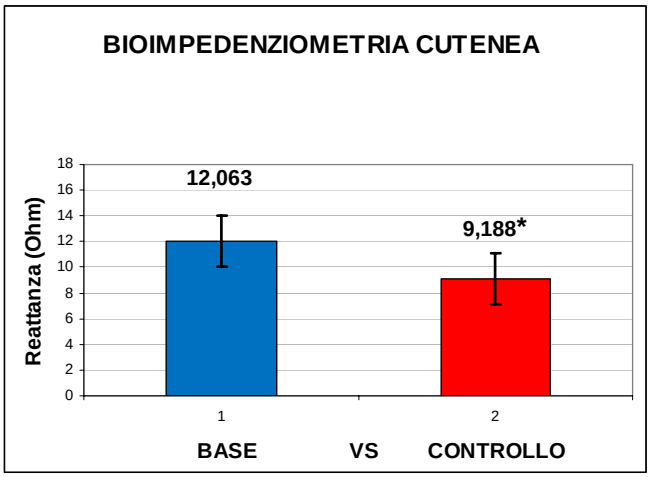

Fig. 2: Graphic representation of the changes in the reactance value before and after treatment with Cibides Lipogel. Data are expressed as mean +/- SD.

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