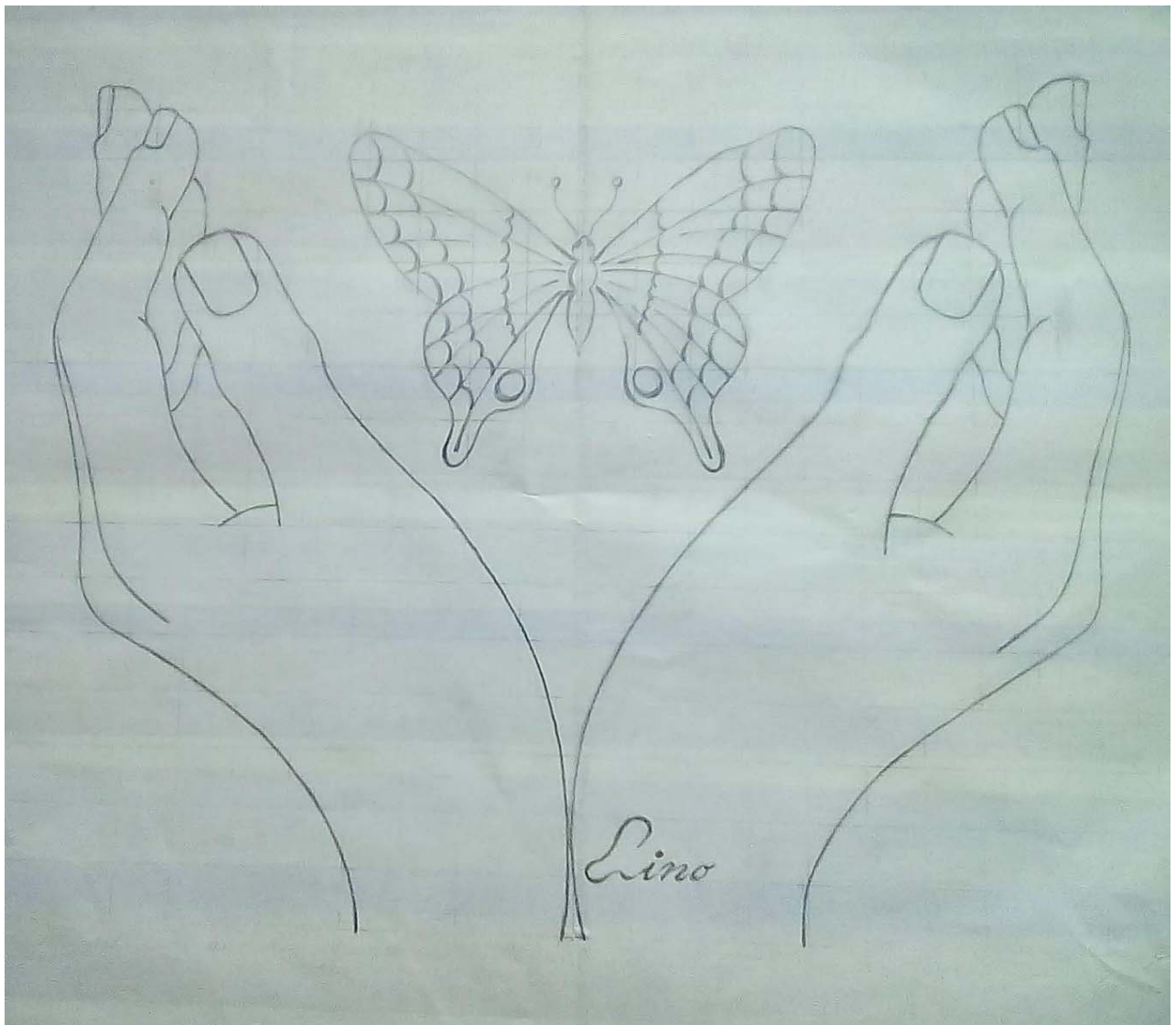


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Safety of Viviven on Chronic Venous Insufficiency explored by HRV.

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KEYWORDS: Venous Insufficiency, elderly, safety.

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ABSTRACT

Background: Chronic venous insufficiency (CVI) is secondary to a decompensation of the functioning of peripheral veins. It is an alteration of the venous circulation of the lower limbs, in which the return of blood towards the heart is hindered by disorders that deteriorate the functionality of the valves of the veins, not only in the orthostatic position, but also in the clinostatic position. The IVC, however, it is not just about veins - patencies and features parietal and valvular (vascular factors) -, but also any cause that alters the venous return - muscle pump of the foot, calf and thigh, changes in joint motility and connective tissue (factors extravascular). **Aim:** The aim of this study is to evaluate the cardiovascular safety of the Viviven nutraceutical in subjects with chronic venous insufficiency administered orally once a day.

Materials and Methods: 25 subjects (9 men and 16 women) with mild to moderate chronic venous insufficiency were enrolled for the study. Due to pandemic restrictions and the negative effect on the psychological frailty of elderly subjects, the short protocol was terminated by only 10 patients (3 men and 7 women). The subjects enrolled and followed up in follow-up had a mean age of 84.7 ± 11.3 years (with a minimum of 65 years and a maximum of 98 years). The study was started in January 2022, carrying out an electrocardiogram, clinical evaluation and echocolor doppler at enrollment and after follow-up (1 week for ecg and 3 months for color doppler echo). and the T peak to T end index. We calculated the QTs with the tangent method, in which the end of the T wave is identified by the intersection of a line extrapolated from the isoelectric line and tangent to the line that touches the terminal part of the T wave at the point of minimum slope. After the QT, the RR intervals were calculated by measuring the distance in milliseconds from the R of the first QRS complex to the second R of the second QRS complex. The Tpeak to T end index is evaluated by measuring in milliseconds, the distance between the peak of the T wave and the end of the wave itself on the electrocardiographic trace. **Results:** The results of our study did not highlight a statistically significant variation in the value of the RR interval, the QT interval and the T peak to T end index using the different calculation formulas. The study showed that the calculation of the QT and the Tp / Te interval with the different formulas and in the different age groups, in patients with venous insufficiency treated with VIVIVEN, does not determine a statistically significant variation of the main arrhythmic indices and confirms the safety of the drug even in the extreme age groups. **Discussion:** The

study on venous insufficiency carried out by us made it possible to clarify that the assessment of QT and Tp / Te is not an indication to limit the pharmacological prescription of Viviven in elderly patients with comorbidities. **Conclusions:** The use of QT and Tpeak to T end measurement has for years become common in the specialist field for the assessment of arrhythmic risk. The importance of this assessment lies in the possibility of missing drug prescriptions due to statistically significant changes in the QT and Tpeak / Tend values index on the electrocardiographic trace after drug treatment. This aspect is of considerable importance in the taxation of drug therapy in elderly patients suffering from frailty and in polypharmacological treatment. **Limitation of the study:** The limitation of the study is related to the limited representativeness of patients who have finished the follow-up due to the restrictions induced by the covid-19 pandemic and the logistical difficulties for the ultrasound outpatient control. The statistical analysis carried out with parametric tests for small groups (paired T test). No significative modificiation about PSV are noted using Echo doppler evaluation.

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