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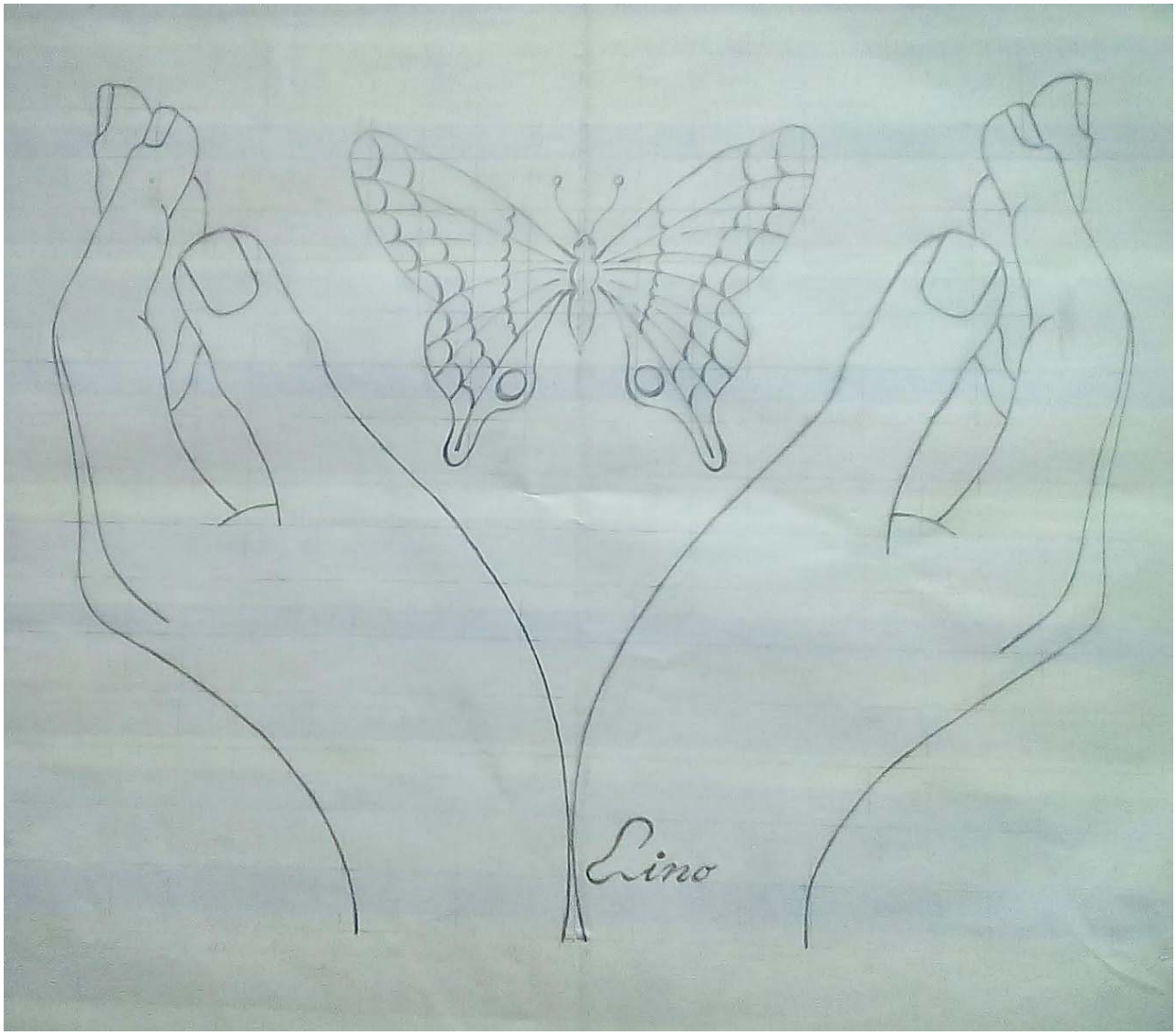

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Nutraceutical treatments for Hypercholesterolemia in dialysed patients.

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ABSTRACT

Background: Chronic renal failure is an increasingly common disease in the elderly population. this disease often determines the need for dialysis treatment. Numerous studies show an increased cardiovascular risk and arrhythmic risk in dialysis patients. Our previous studies have shown that a specific diet improves the effect of dialysis but determines a reduction in HDL cholesterol with a consequent increase in cardiovascular risk in subjects who cannot take standard therapy with statins. **Aim:** The purpose of our study is to evaluate the effect of medronis cholesterol on the lipid profile and in particular on the HDL cholesterol value. **Materials and Methods:** our study involved 30 dialysis patients to evaluate changes in lipid profile before and after medronis cholesterol treatment. All patients will undergo non-invasive electrocardiographic recording in order to evaluate the effect of medronis cholesterol on autonomic tone. The Neuro-vegetative cardiovascular modulation was evaluated by EKG analysis of the Heart Rate Variability (HRV) before and after the treatment. The treatment is performed in two daily administration, for 1 month,). Data analysis software: Recorded data were analyzed with cardiolab xai-medica software for HRV linear analysis, and with kubios software for the HRV non-linear analysis. Statistical analysis: Statistical analysis was performed with SigmaStat 3.5 software for Windows. Paired T-test for quantitative variables were used to compare the effect of the treatment. Statistical significance was fixed at $P < 0.05$. Results: The results of our pilot study conducted on 10 patients allowed us to highlight a statistically significant reduction in total cholesterol not associated with a statistically significant variation in HDL cholesterol values. Normalization of total cholesterol in patients who cannot take standard statin therapy due to the severity of chronic kidney disease is a significant clinical advantage as it allows for a correction of cardiovascular risk. **Discussion and Conclusion:** The preliminary data in our possession underline the significant reduction in total cholesterol after only 1 month of therapy not associated with a statistically significant change in HDL cholesterol values. The small number of the sample currently under examination does not allow us to make a conclusive evaluation. However, further studies are underway to extend the statistical sample and verify any statistical significance.

Background: Chronic renal failure is a disease increasingly present in the elderly population. This disease often determines the need for dialysis treatment. Numerous studies have shown an increased cardiovascular risk and arrhythmic risk in dialysis patients. Our previous studies have shown that a specific diet improves the effect of dialysis but determines a reduction in HDL colosterol with a consequent increase in cardiovascular risk.

Aim: The aim of our study is to evaluate the effect of medronis cholesterol on the lipid profile and in particular on the HDL cholesterol value. Currently, 10 patients 8 men and 2 women with an average age of 65.3 years old with end-stage renal failure in dialysis associated with dyslipidemia are enrolled in our pilot study. The study began in March 2019.

Materials and Methods: Our project plans to enroll 30 patients suffering from end-stage renal failure undergoing dialysis. Currently our pilot study has been carried out by collecting and processing the data of patients belonging to the dialysis center of the Alfredo Fiorini hospital in terracina directed by MD Vittorio Stranges and MD Mobilia Pasquale. The data from our study therefore relate to 10 patients with an average age of 65.3 years. All enrolled patients have an elevated cardiovascular risk profile and have a normal blood pressure reading. All patients underwent non-invasive 12-lead digital electrocardiographic recording with the medical xai device in order to evaluate the effect of medronis cholesterol on autonomic tone and to perform laboratory tests to evaluate total cholesterol, LDL cholesterol, HDL cholesterol and triglicerids. All patients provided written informed consent. The study features a run-in period during which all patients undergo pre-ECG evaluation and screening for dyslipidemia in order to identify patients indicated for medronis cholesterol treatment.

The data collection was carried out by integrating the paper material with a database specifically created for the insertion of laboratory data and instrumental tests related to the procedure. The need to create the database is linked to the possibility of performing preliminary data analyzes using simple " filter " functions and checking the homogeneity of the data entered and exporting the data in a way compatible with the statistical analysis software carried out with sigmastat version 3.5 for Windows XP. The data collection was carried out at the same time as the request for informed consent processed by us.

As regards the use of scale, it has been standardized to the international reference system for laboratory tests and instrumental tests.

Screening eligibility requirements included the age of at least 18. The exclusion criteria included treatment with anti-arrhythmic drugs for the assessment of heart rate variability in heart disease patients to avoid distortions in heart rate variability.

Statistic analysis

We used the Paired T test to analyze the numerical data deriving from pre and post

treatment recordings in the same subjects enrolled in the study. The Paired T test allows you to perform comparative statistical analyzes on small groups. (Tab. 1).

Results: From November 2018, until January 2019, a total of 30 patients entered the run-in period. All patients meet the criteria for the study. No patients were randomized in error or enrolled in closed sites due to serious violations of good clinical practice. Most patients received recommended drug therapy for chronic renal failure disease.

The treatment was well tolerated in routine clinical practice. All patients started study drug and no subjects were excluded after the patient run-in period due to the absence of transient adverse events. We found a statistically significant variation in total cholesterol values in the enrolled subjects. There were no statistically significant changes from baseline in LDL and HDL cholesterol values.

Discussion and Conclusion: Our study was designed to provide evidence to support the efficacy of medronis cholesterol treatment in managing cholesterol in patients with CRF. The data show that the treatment statistically significantly improves the lipid profile regarding total cholesterol. There is no statistically significant change in LDL, HDL and triglyceride cholesterol values. This experience has led us to use medronis cholesterol in patients with CRF and treated with dialysis therapy who cannot take conventional statin therapy. Our data gives comfortable results, but further evaluation is needed to have conclusive results.

LIMITATIONS OF THE STUDY: The only limitation of the study concerns the small number of the sample currently enrolled. The study is being continued at other Dialysis Centers in order to increase the statistical sample under examination. The preliminary data in our possession do not allow us a conclusive evaluation due to the small number of patients currently enrolled and studied.

We are waiting to receive the data of the patients enrolled at the Latina dialysis center in order to reach the sample size of the 30 subjects enrolled.

Conflict of Interest: none declared

TABLES

	CONTROL ± SD	EFFECT ± SD	Probability (P)
Total Cholesterol	136,600 ± 30,758	121,200 ± 28,901	0,006*
LDL Cholesterol	73,300 ± 37,366	70,500 ± 23,449	0,781
HDL Cholesterol	39,700 ± 14,111	32,900 ± 8,569	0,060
Triglycerides	86,400 ± 37,933	119,700 ± 58,266	0,074
Creatinine	9,073 ± 1,930	9,876 ± 2,076	0,200

Table : 1 Descriptive Statistics about Cholesterol profile.

FIGURES

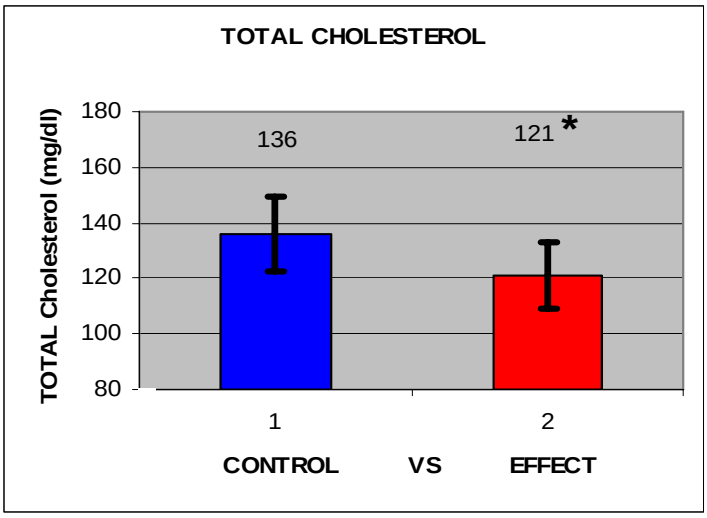

Fig. 1: Descriptive statistic about Total cholesterol.

Data are expressed as mean ± Standard Deviation.

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