EFFECT OF EFLA®943 IN ADULT TWINS WITH MILD HYPERTENSION

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Introduction

Olive leaves have been used in folk medicine in a variety of indications [1]. Modern phytotherapy indicates the use of olive leaves for hypertensive states and as a diuretic agent [2]. Numerous studies have shown their several properties and support their antihypertensive, antihyperglycemic and anti-inflammatory activities [2, 3, 4].

Hypertension is a major risk factor for cardiovascular diseases. An early intervention with a non-pharmacological therapy – lifestyle modification, diet - is nowadays generally considered as wise for persons with elevated blood pressure, with regard to possible additional risk factors [5]. However, a significant number of deaths attributable to hypertension occur in persons who are not diagnosed as hypertensive but whose blood pressure is above the optimal level of 120/80 mmHg. Therefore, lowering blood pressure levels even in the high-normal range is recommended as well, with lifestyle modifications being the first-line therapy.

Olive leaves' components possess properties that allow a dietary intervention in the above mentioned sense and make it plausible with respect to nutritional physiology. EFLA®943 olive leaf special extract contains the natural active ingredients of olive leaves in concentrated form.

Objective

The aim of this study was to assess the effect of EFLA®943 olive leaf special extract as food supplement in the context of dietary measures for adults with mild hypertension.

Materials and Methods

The study was conducted by the HealthTwiSt GmbH, D-Berlin, in 2004 and 2005. Voluntarily enrolled were 20 monozygotic twin pairs aged 18-60 with blood pressure values above the optimal level (RRdiast.: ≥80 mmHg; RRsyst.: ≥120 mmHg). Exclusion criteria included pharmacological treatment for hypertension and/or blood pressure values >95 mmHg RRdiast, or >160 mmHg RRsyst.

EFLA®943 coated tablets contain 500 mg of olive leaf special extract EFLA®943 as active principle (Oleuropein 18.0-26.0% w/w, Frutarom Switzerland Ltd., CH-Wädenswil).

After screening, twin pairs were randomly divided into 2 groups. In Group 1 non-pharmacological measures (dietary recommendations, lifestyle change) were compared to the additional daily consumption of a tablet in the co-twin. In Group 2 dose effects were tested between twins taking one tablet once daily compared to the co-twin taking one tablet twice daily. The test period lasted 8 weeks.

Blood pressure was recorded at baseline and after 1, 2, 4, 6 and 8 weeks of intervention at rest with a sphygmomanometer. The mean value of three readings was used for data analysis. Blood samples were collected at baseline and after 4 and 8 weeks and lipid profile measured.

Statistical evaluation of collected data was performed using SPSS v.12. Primarily, each dataset was analysed for intra-pair differences according to the co-twin control design. Differences within each twin pair at the beginning of the study were used for standardisation, variations of the pair differences during the course of the study were reported relating to the start difference. Mean values of differences for each twin pair group at measurement time points during the study were obtained. Secondarily, data were analysed using the dosage as grouping parameter by the general linear models procedure with repeated measurements.

Satisfaction and tolerance of the treatment were recorded.

Results

Effect on blood pressure

Analysis of blood pressure values according to the parameter "intra-pair difference" resulted in reduction of blood pressure values during the study period. The following statistically significant results were found: within the twin pair group treated with 500 mg EFLA®943 compared to control (Group 1), the maximal blood pressure decrease that occurred was of 6 mmHg systolic (p=0.001, n=10) and 5 mmHg diastolic (p=0.006, n=10). The maximal reduction amounted to 13 mmHg systolic (p=0.001, n=10) and 5 mmHg diastolic (p=0.006, n=10) in twin pairs treated with 1000 mg compared to 500 mg EFLA®943 (Group 2). Under the assumption of additive dose-effect relationship, an approximated blood pressure decrease of 19 mmHg and 10 mmHg can be expected, respectively.

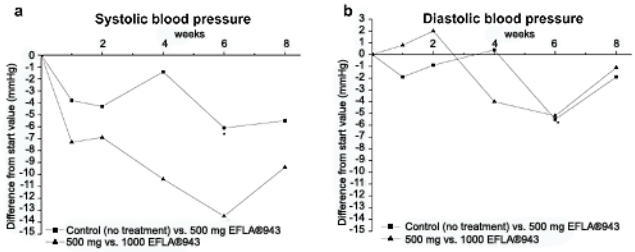


Figure 1. Reduction of blood pressure values, systolic (a) and diastolic (b) with respect to initial values (study start). Data represent mean of differences within twin pairs of Group 1 (■), controls (no treatment) vs. 500 mg EFLA®943, and Group 2 (▲), 500 mg vs. 1000 mg EFLA®943. (* statistically significant difference, $p < 0.05$).

In addition, data analysis with dosage as grouping parameter also shows the decrease in blood pressure values (Fig. 2).

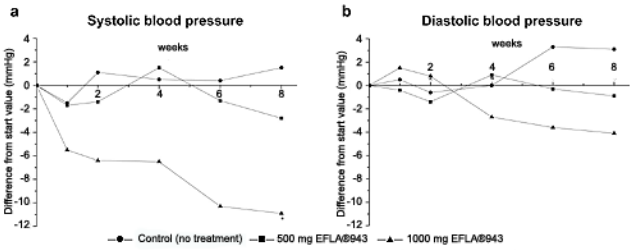
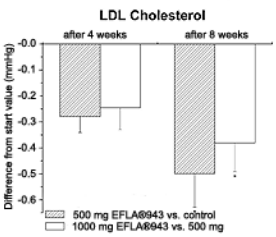


Figure 2. Reduction of mean blood pressure values, systolic (a) and diastolic (b), of adults treated with 500 mg (■) and 1000 mg (▲) EFLA®943 compared to controls (●) with respect to initial values (study start). (* statistically significant difference, $p < 0.05$).

The overall trend shows a continuous decrease of the blood pressure over the course of the study. This could be observed for both systolic and diastolic blood pressure values, and the decrease was much more marked in participants treated with 1000 mg EFLA®943. A statistically significant decrease in systolic blood pressure of about 11 mmHg (8%) was observed at the end of the study period in adults taking 1000 mg EFLA®943 (p=0.01, n=10). No significant change of diastolic blood pressure was observed for all the dosage groups.

Effect on serum lipids

Among the parameters of the lipid profile, a significant reduction of LDL cholesterol by 0.5 mmol/l (19.3 mg/dl) was observed in the group of twin pairs treated with 500 mg EFLA®943 vs. control (Group 1) at 8 weeks.



An additional decrease of 0.38 mmol/l (14.7 mg/dl) resulted with 1000 mg EFLA®943 (Group 2).

Figure 3. Reduction of mean LDL cholesterol values with respect to baseline (study start), after 4 and 8 weeks of intervention, respectively. Data represent means ± SEM of LDL differences within twin pairs of Group 1 (▨), controls (no treatment) vs. 500 mg EFLA®943, and Group 2 (▭), 500 mg vs. 1000 mg EFLA®943. (* statistically significant difference, $p < 0.05$).

Conclusion

The results of the study support the beneficial effect of the olive leaf special extract EFLA®943 as dietary supplement in the context of a non-pharmacological approach for the treatment of mild hypertensive states.

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