



Study summary

Effect of Benolea® (EFLA®943) in adult twins with mild hypertension

Objective

The aim of this study was to assess the effect of Benolea® (EFLA® 943) patented Olive Leaf Extract as food supplement for adults with mild hypertension.

Study design

The study was conducted by the HealthTwiSt GmbH, D-Berlin, in 2004/2005. Enrolled were 20 monozygotic twin pairs aged 18-60 with blood pressure values above the optimal level (RRdiast.: ≥ 80 mmHg; RRsyst.: ≥ 120 mmHg). Tablets contained 500 mg of Benolea® as active principle. After screening, twin pairs were randomly divided into two groups. In Group 1 non-pharmacological measures (dietary recommendations, lifestyle change) were compared to the daily consumption of one tablet in the co-twin (control vs. 500 mg Benolea®). In Group 2 dose effects were tested between twins taking one tablet once daily compared to the co-twin taking one tablet twice daily (500 mg vs. 1000 mg Benolea®). The test period lasted 8 weeks. Blood pressure was recorded once per week starting at baseline. Blood samples were collected at baseline and after 4 and 8 weeks and lipid profiles measured.

Statistical evaluation of collected data was performed for intra-pair differences according to the co-twin control design. Side/adverse effects were recorded.

Results

Effect on blood pressure

Analysis of blood pressure values resulted in reduction of blood pressure values during the study period. The following statistically significant results were found: in Group 1, the maximal blood pressure decrease that occurred was of 6 mmHg systolic and 5 mmHg diastolic.

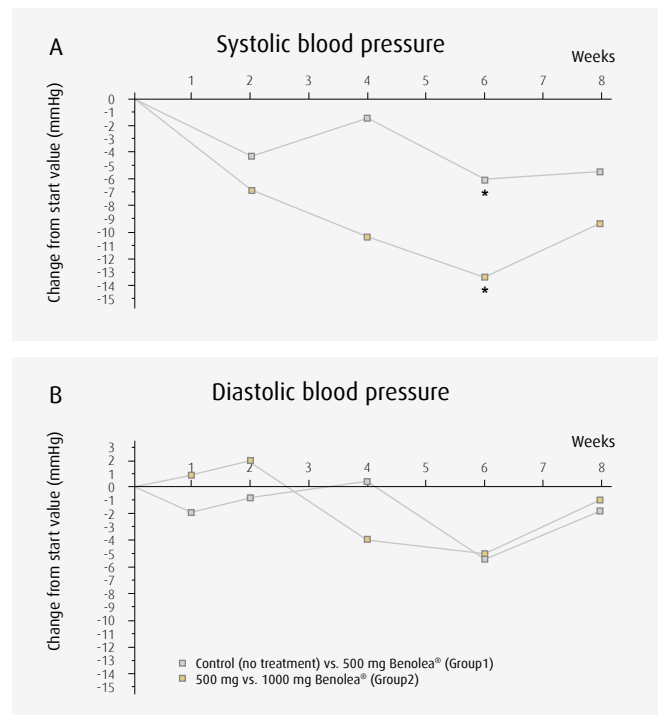


Figure 1: Reduction of blood pressure values, systolic (A) and diastolic (B) with respect to initial values (study start). Data represent mean of differences within twin pairs of Group 1 (□) and Group 2 (■). (*statistically significant difference, $p < 0.05$).



The maximal reduction amounted to 13 mmHg systolic and 5 mmHg diastolic in Group 2.

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 Group 1 at 8 weeks. An additional decrease of 0.38 mmol/l (14.7 mg/dl) resulted with 1000 mg Benolea[®] (Group 2).

Safety and tolerability

The extract was well tolerated throughout the study period.

Conclusion

The results of the study support the beneficial effect of the Olive Leaf Extract Benolea[®] as dietary supplement in the context of a non-pharmacological approach for the treatment of mild hypertensive conditions.

For references please contact:
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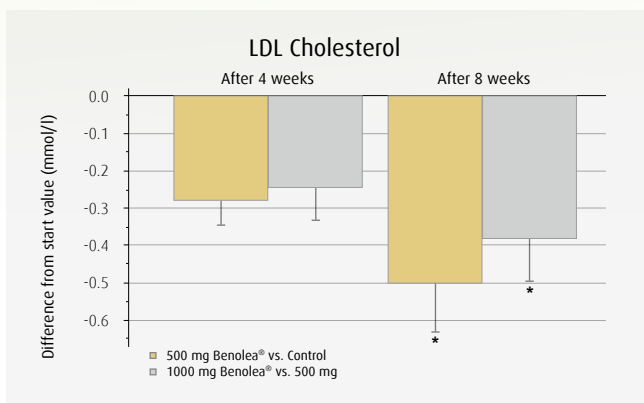


Figure 2: Reduction of mean LDL cholesterol values with respect to baseline (study start), after 4 and 8 weeks of intervention, respectively. Data represent means \pm SEM of LDL differences within twin pairs of Group 1 (■), and Group 2 (■). (* statistically significant difference, $p < 0.05$).

