

Study summary

Blood pressure-reducing and lipid-lowering effect of Benolea® (EFLA®943) in stage-1 hypertension

Objective

Benolea® is an olive leaf extract used as natural agent for healthy blood pressure levels. The underlying study assessed the blood pressure reducing effect of Benolea® in human volunteers with Stage-1 hypertension. Benolea® is compared to the widely used pharmaceutical Captopril. In addition, the lipid-lowering effect, safety and tolerability of Benolea® were evaluated.

Study design

The study was conducted by Dexa Medica Pharmaceuticals Manufacturers in Indonesia and was randomized, double-blind, double-dummy and active-controlled. 232 volunteers participated in the study. Participants were 25 to 60 years old with stage-1 hypertension (SBP; systolic blood pressure) 140-159 mmHg, and/or DBP (diastolic blood pressure) 90-99 mmHg) and were not taking any medication or asked to stop it upon consent. A 4 weeks run-in period without treatment was followed by a treatment of 8 weeks. During the treatment period, participants took Benolea® 2 times daily a 500 mg caplet, or Captopril 2 times per day a 12.5 mg tablet. After 2 weeks, if participants showed no response to Captopril, they received a double dose.

Dietary advice was given to help participants manage their hypertension. Measured variables were: clinic SBP and DBP, lipid profile (fasting plasma LDL-, HDL-, and total cholesterol, and triglyceride levels). To evaluate safety, adverse events and changes in laboratory parameters (routine hematology, serum electrolytes, liver and renal function) were monitored.

Results

Blood pressure-lowering effect

Both Benolea® and Captopril clearly lowered SBP compared to baseline. The reduction in the natural treatment group (Benolea®) was slightly smaller than in the pharmaceutical group (Captopril) (Fig.1).

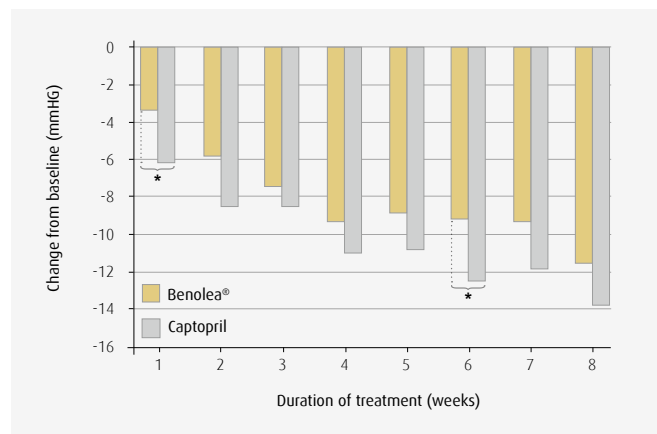


Figure 1: Reduction of SBP values from study start in Benolea® and in Captopril group. (* $p < 0.05$, significant differences between groups were based on statistical analyses by independent t-test)

In subjects with higher initial SBP (>145 mmHg), the reduction in SBP appeared equal with Benolea® (N=37) as with Captopril (N=35) (data not shown).



Lipid-lowering effect

With regards to lipid profile, Benolea[®] significantly reduced total cholesterol and triglyceride levels (Fig.2). Particularly in participants with high triglyceride levels (>200 mg/dl) the reduction was remarkable (-53.13 mg/dl).

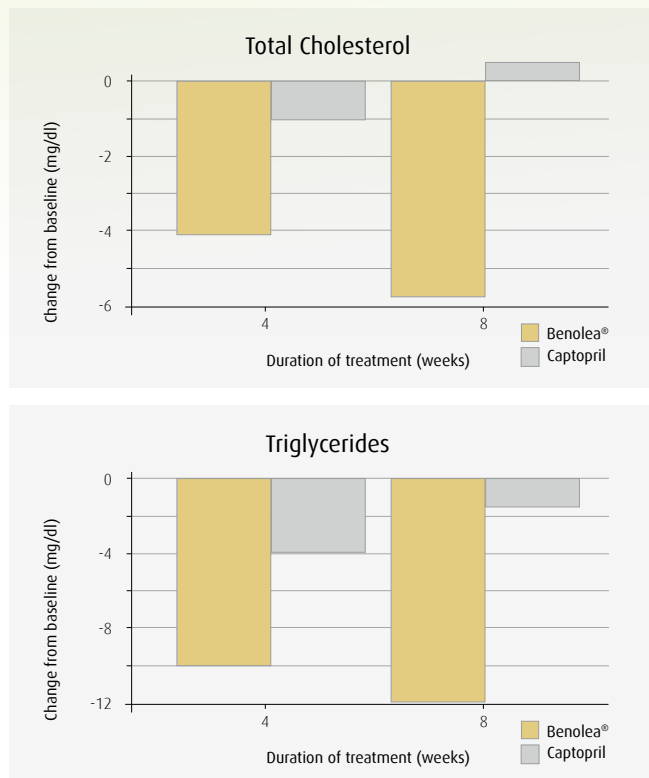


Figure 2: Reduction of total cholesterol and triglycerides values with respect to study start, after 4 and 8 weeks of intervention, in Benolea[®] and in Captopril group.

Safety and tolerability

The extract was safe and well tolerated throughout the study period.

Conclusion

The results of this clinical study show that the Olive Leaf Extract Benolea[®] lowers blood pressure in persons with mild elevated values (stage-1 hypertension): the effect was similar to standard antihypertensive therapy Captopril, especially in those with higher systolic blood pressure. Moreover, the extract positively influences the lipid profile of this hypertensive population, is safe and well tolerated. Previously, a preliminary study in monozygotic twins had reported the benefits of Benolea[®] in lowering blood pressure and LDL- cholesterol in borderline hypertension. The present findings confirm the blood pressure-reducing and lipid-lowering properties of the extract and additionally show its efficacy in stage-1 hypertensive people.

For references please contact:
health.switzerland@frutarom.com

