Three-arm, placebo controlled, randomized clinical trial evaluating the metabolic effect of a bergamot standardized flavonoid extract combined with artichoke and phytosterols in dyslipidemic overweight subjects

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Study objective:
Polyphenols are an important category of natural compounds able to modulate inflammatory pathways.

Our double-blind, placebo-controlled, parallel-group clinical trial aimed to test the effect of a combined nutraceutical (patent n° IT000422673/EP 3116520A) containing bergamot extract (120 mg flavonoids), 120 mg phytosterols, 20 mg vitamin C and 2 mg chlorogenic acid from dry artichoke extract on 90 overweight subjects with dyslipidemia.

Method:
Participants were randomly allocated to treatment with two pills of either active treatment or placebo, or a combination of both (a pill per treatment).

Results:
At 8-week visit, all groups significantly differed for TG, with lower levels in the high-dose group in comparison with placebo (p<0.05). All patients randomized to receive either low-dose or high-dose active treatment experienced a significant decrease in LDL-C versus both baseline and placebo treatment. Furthermore, in the high-dose group, a significant reduction was found between the baseline and follow-up levels of TC, non HDL-C, Gamma-GT, hs-CRP and TNF-apha. TC levels significantly decreased also in comparison with placebo (p<0.05 always). At 24-week follow-up, TG levels maintained lower than baseline in all groups (p<0.05). All patients allocated to either low-dose or high-dose active treatment experienced a significant decrease in TG, LDL-C and HOMA-IR versus baseline and placebo. Furthermore, in subjects taking high-dose active treatment adiponectin significantly increased while TC, non HDL-C, FPI, leptin, leptin/adiponectin ratio, hs-CRP and TNF-apha were significantly reduced as compared with placebo and baseline (p<0.05 always).

Conclusion:
In conclusion, the tested nutraceutical showed to improve lipid and glucose metabolism, adipokines pattern and systemic inflammation in dyslipidemic overweight subjects.

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Conflicts of interest:
Costanza Riscioni is a member of Esserre Pharma srl and contributed to the realization of this poster.

The other authors don't have any conflict of interest in this study.