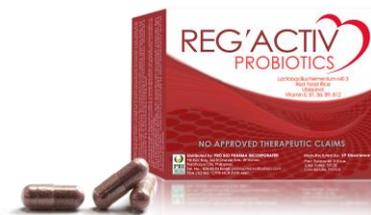


Effect of a probiotic formulation combining *Lactobacillus fermentum* ME-3, Ubiquinol and Monacolin K on cardiovascular risk factors in human subjects

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OBJECTIVES

Lactobacillus fermentum ME-3 is a patented probiotic strain isolated in Estonia, with demonstrated antioxidative activity in humans (improvement of glutathione redox ratio, lowering of peroxidized lipoproteins and oxidized LDL levels). We investigated the antiatherogenic effects of a new capsule formulation, Reg'Activ Cholesterol, which combines *L. fermentum* ME-3, ubiquinol (Kaneka QH™), L-cysteine and vitamins.

METHODS

Open label pilot clinical trial, 25 clinically asymptomatic subjects with mild hypercholesterolemia received two capsules per day during four weeks. Blood parameters related to hyperlipidemia, inflammation and oxidative stress were measured at day 0 and day 28.

REG'ACTIV CHOLESTEROL REDUCES HYPERLIPIDEMIA, INFLAMMATION AND OXIDATION

Markers related to hyperlipidemia

Reduction of total cholesterol, LDL cholesterol, triglycerides. Decrease of TG/HDL ratio, associated with insulin resistance.

Hyperlipidemia	Day 0	Day 28	
Total Cholesterol (mmol/L)	6,6±1,0	5,7±0,8 p<0,0001	↓ 13%
LDL-Chol (mmol/L)	4,5±0,9	3,6±0,8 p<0,0001	↓ 20%
HDL-Chol (mmol/L)	1,66±0,33	1,70±0,35	NS 2,4%
TG (mmol/L)	1,5±0,4	1,3±0,3 p<0,03	↓ 13%
TG/HDL-Chol	1,0±0,4	0,8±0,3 p<0,03	↓ 20%

Markers related to inflammation

Decrease of hsCRP and IL-6. Increase of anti-inflammatory cytokine IL-10.

Inflammatory markers	Day 0	Day 28	
hsCRP (mg/L)	2,31±1,44	1,88±0,95 p=0,035	↓ 18,6%
HbA1c %	5,68±0,21	5,51±0,20 p=0,043	↓ 3%
IL-6 (pg/ml)	2,2±0,6	1,9±0,5 p<0,05	↓ 13%
IL-10 (pg/ml)	6,4±2,0	7,3±2,6 p=0,034	↑ 14%

Markers related to oxidation

Decrease of oxLDL and oxidative stress markers.

Oxidative stress	Day 0	Day 28	
oxLDL (U/L)	80,58±16,69	65,77±12,6 p<0,0003	↓ 19%
TPX (total peroxides, mmol/L)	560,4±318,0	468,5±230,4 p=0,009	↓ 16%
OSI index	43,8±26,1	35,8±18,4 p=0,012	↓ 18%

CONCLUSIONS

After only four weeks, consumption of Reg'Activ Cholesterol, a new formulation combining *L. fermentum* ME-3, Ubiquinol, Monacolin K, L-cysteine and vitamins, lead to a substantial improvement of blood parameters related to cardiovascular disease risk. The beneficial effects of the formulation were seen not only on parameters related to hyperlipidemia, but also on markers related to inflammation and oxidative stress, which are known as main contributors to atherogenesis. The study also provided indication that *Lactobacillus fermentum* ME-3 combined with the active ingredients of the formulation, could be beneficial in the context of insulin resistance and metabolic syndrome.

PREVIOUS STUDIES ON *L. FERMENTUM* ME-3

Nutrition Journal 2005, vol. 4(22) - **Evaluation of the functional efficacy of an antioxidative probiotic in healthy volunteers** Antioxidative effects of ME-3 on healthy volunteers: improvement of parameters associated with atherosclerosis.

Proceedings of the 4th European Congress on food, 2008 - Probiotics, oxidative stress, inflammation and diseases Improvement of oxidative stress markers in the blood and in the skin of atopic dermatitis patients; improvement of prognosis in elderly patients recovering from a stroke.

Microbial Ecology in Health and Disease 2009, vol. 21 - **Lactobacillus fermentum ME-3: an anti-microbial and anti-oxidative probiotic** Review on *L. fermentum* ME-3 effects.

Central European Journal of Biology 2011, vol. 6(1) - **An antioxidant probiotic reduces post-prandial lipemia and oxidative stress** *L. fermentum* ME-3 improves post-prandial oxidative stress, triglyceride and lipoprotein status.



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